i-STAT®1
System Manual

Abbott
Point of Care

Patents: <u>www.abbott.us/patents</u>

Symbol Technologies Corporation is the owner of US Patent No. 5,532,469.

Trademarks

i-STAT is a registered trademark of the Abbott Group of Companies in various jurisdictions. Windows is a registered trademark of Microsoft Corporation.

i-STAT 1 SYSTEM MANUAL CONFIGURATION

Please ensure that the contents of your System Manual are complete and up to date. In the event that your System Manual does not contain the current configuration, it is recommended that you contact your i-STAT support provider.

As of May 2017, your i-STAT®1 System Manual should be configured with the contents as listed below and in the order shown.

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This Manual

This manual describes the i-STAT®1 Analyzer and the Central Data Station software. Related sections are grouped behind tabs.

Intended Use

The i-STAT 1 Analyzer is intended for use with i-STAT cartridges for the *in vitro* quantification of various analytes in whole blood. Analyzers and cartridges should be used by healthcare professionals trained and certified to use the system and should be used according to the facility's policies and procedures.

The i-STAT System is for *in vitro* diagnostics use. Caution: Federal law restricts this device to sale by or on the order of a licensed practitioner.

FDA Test Categorization

With the i-STAT 1 System, the FDA has categorized the tests included on the i-STAT G, Crea, E3+, EC4+, 6+, and CHEM8+ cartridges as waived when testing is performed using venous whole blood samples collected in lithium heparin evacuated tubes. Other venous whole blood samples, capillary and/or arterial samples tested using these same cartridges on the i-STAT 1 System are categorized by the FDA as moderate complexity.

For waived testing, laboratories are required to follow the manufacturer's requirements for the testing. They may elect to perform additional quality control testing (such as the QC required for a moderate complexity test) but this does not change the FDA categorization of the test as waived or release the laboratory's responsibility to follow the manufacturer's instructions for it as a waived test.

Other testing performed with the i-STAT 1 System (other than the testing performed using the aforementioned cartridges) is FDA categorized as "moderate complexity".

Overview of the i-STAT System

The i-STAT System incorporates a comprehensive group of components needed to perform blood analysis at the point of care. A portable handheld analyzer, a cartridge with the required tests, and 2-3 drops of blood will allow the caregiver to view quantitative test results for blood gas, chemistry and coagulation tests in approximately two minutes.

Portable printers and infrared communication devices allow all patient information obtained at the bedside to be printed on demand and transmitted to centralized information systems for record keeping and billing.

The Central Data Station program provides system management tools including real-time monitoring of testing and operator competency.
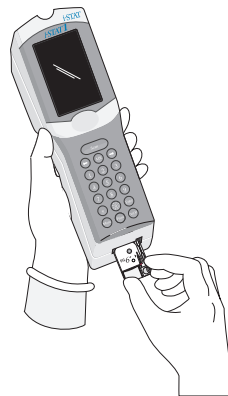
Components   The i-STAT System consists of:

- ✧ i-STAT Cartridges
- ✧ i-STAT 1 Analyzer
- ✧ Portable Printer
- ✧ Quality Assurance Materials

  - • Electronic Simulator
  - • Control Solutions
  - • Calibration Verification Set (for cartridges)
- ✧ Data Management System

  - • i-STAT 1 Downloader
  - • i-STAT 1 Downloader/Recharger
  - • Data Manager

    - ➢ Central Data Station (data management software for cartridges)
- ✧ Data Manager Printer
- ✧ LIS/HIS Interface Software

Selection of Components   The selection of system components is dependent on factors unique to each facility such as:

- ✧ Types of tests to be performed
- ✧ Number of testing sites
- ✧ Number of tests per site
- ✧ System administration requirements

Summary of the Procedure   To perform cartridge testing, the operator fills a cartridge with sample, seals the cartridge with its snap closure, and inserts the cartridge into the analyzer. Inserting the cartridge activates the analyzer. Alternatively, the cartridge test cycle can be initiated from the keypad/menu system. The unit-use cartridge contains all components to perform one or more tests including: calibrating solution, sample handling system, sensors and reagents. The analyzer automatically controls all steps in the testing cycle, which may include: fluid movement, reagent mixing, calibration and thermal control. Quality checks are performed continuously throughout the test cycle. Operator and patient IDs and patient chart information can be entered. When the test cycle is completed, results are displayed and the test record is stored.

Data Management   Test records can be transmitted to the Data Manager where they can be printed and/or transmitted to the Laboratory Information System or Hospital Information System. An optional portable printer enables the operator to print results at the point of care.

Interfacing   The Data Manager can be interfaced to a Laboratory Information System (LIS) or Hospital Information System (HIS) to automate billing and patient record keeping.

Note Regarding System Reliability   The i-STAT System automatically runs a comprehensive set of quality checks of analyzer and cartridge performance each time a sample is tested. This internal quality system will suppress results if the analyzer or cartridge does not meet certain internal specifications (see Quality Control section in System Manual for detailed information). To minimize the probability of delivering a result with medically significant error the internal specifications are very stringent. It is typical for the system to suppress a very small percentage of results in normal operation given the stringency of these specifications. If however the analyzer or cartridges have been compromised, results may be persistently suppressed, and one or the other must be replaced to restore normal operating conditions. **Where unavailability of results while awaiting replacement of analyzers or cartridges is unacceptable, Abbott Point of Care Inc. recommends maintaining both a backup i-STAT System analyzer and cartridges from an alternate lot number.**

Symbols   Symbols can be helpful in reducing the necessity for translating important information into multiple languages, particularly where space is limited. The following symbols may be found on components of the i-STAT System.

Symbol	Definition
⚠	Attention: See instructions for use.
⚡	Caution: Risk of electrical shock.
☀	Laser radiation hazard symbol.
☣	Biological Risks.
🌡	Temperature limitations. The upper and lower limits for storage are adjacent to upper and lower arms.
🌡	Upper limit of temperature. The upper limit for storage is adjacent to the upper arm
⧖	Use by or expiration date. An expiration date expressed as YYYY-MM-DD means the last day the product can be used. An expiration date expressed as YYYY-MM means the product cannot be used past the last day of the month specified.

Symbol	Definition
LOT	Manufacturer's lot number or batch code. The lot number or batch will appear adjacent to this symbol.
REF	Catalog number, list number, or reference number. The number adjacent to this symbol is used to reorder the product.
SN	Serial number. The serial number will appear adjacent to this symbol.
MN	Model number. The model number will appear adjacent to this symbol.
	Date of manufacture.
	Manufacturer
IVD	In vitro diagnostic medical device.
EC REP	Authorized Representative for Regulatory Affairs in the European Community.
	Contains sufficient for < n > tests.
===	Direct Current (DC)
∿	Alternating Current (AC)
☐	Class II Construction
	Consult instructions for use or see System Manual for instructions.
CONTROL	Control
Intertek	Signifies that the product bearing the ETL Listed mark complies with both U.S. and Canadian product safety standards: UL 61010-1: 2nd. Ed. CAN/CSA C22.2 No. 61010.1 2nd. Ed.
immuno	i/immuno: Cartridges bearing this symbol must be run on i-STAT analyzers that also bear this symbol.
	Battery: i-STAT 1 Analyzer low battery icon (flashes on lower left side of display screen).

Symbol	Definition
	Note concerning batteries: The following information is applicable to EEA (European Economic Area) countries: The directive 2006/66/EC requires separate collection of spent batteries. You are requested to dispose those batteries referred to on page 2-3 in accordance with local regulations. This product also contains a separate internal lithium battery that is not intended to be replaced by the user. See page 2-4 under "Additional Power" for more information.
	Separate waste collection for this electrical/electronic item indicated; Equipment manufactured / put on the market after 13 August 2005; Indicates compliance with Article 10(3) of Directive 2002/96/EC (WEEE) for the European Union (EU).
BODxxxx-xx	Born On Date: the label BODxxxx-xx defines the year and month of manufacture.
	Do not reuse.
	This symbol is used for compliance with the China RoHS regulation(s). It indicates in years the Environmentally Friendly Use Period (EFUP) for the labeled electronic medical device product
<< >>	As the Martel Printer is incapable of printing the ↑ or ↓ symbols, this symbol appears on the Martel printout next to results which are outside the action range limits.
14 🔲d	14 days room temperature storage at 18-30ºC
2 🔲m	2 months room temperature storage at 18-30ºC
	Packaging contains cartridges with barcoded pouches
	Signifies that the product bearing the Federal Communications Commission (FCC) logo complies with the specific requirements set forth by the FCC under Rules and Regulations, Title 47, Part 15 Subpart B, for Class A devices.

Symbol	The following symbols are used on the i-STAT 1 keypad.
SCAN	Key used to scan information into the analyzer.
ABC	Key used to enter letters.
ENT	Key used to enter information.
MENU	Key used to access the analyzer's menu.
	Key used to print a test record.
	Key used to turn the analyzer off and on.

Symbol	The following symbols are used on the i-STAT Portable Clinical Analyzer Keypad
DIS	Key used to activate the display.
ENT	Key used to enter information.
PRT	Key used to print a test record.
CLR	Key used to clear an incorrect entry.

Symbol	The following symbols are used on i-STAT Value Assignment Sheets
$\overline{X}$	Mean
R	Range

Symbol	TEST
Na	Sodium
K	Potassium
Cl	Chloride
Glu	Glucose
Lac	Lactate
Crea	Creatinine
pH	pH
PCO_2	Partial pressure of carbon dioxide.
PO_2	Partial pressure of oxygen.
iCa	Ionized Calcium
BUN/UREA	Urea nitrogen/Urea
Hct	Hematocrit
ACTc **Celite ACT**	Activated Clotting Time with Celite® activator.
ACTk **Kaolin ACT**	Activated Clotting Time with Kaolin activator.
PT/INR	Prothrombin Time / International Normalized Ratio
Hb	Hemoglobin
TCO2	Total carbon dioxide concentration.
HCO3	Bicarbonate
BE (b&ecf)	Base excess (b for blood, ecf for extra cellular fluid)

Symbol	TEST
AnGap	Anion Gap
sO2	Oxygen saturation
cTnI	Cardiac Troponin I
CK-MB	Creatine Kinase MB Isoenzyme
BNP	B-type Natriuretic Peptide

Warranty

Abbott Point of Care Inc. warrants this medical product (excluding disposable or consumable supplies) against defects in materials and workmanship for one year from the date of shipment. If Abbott Point of Care Inc. receives notice of such defects during the warranty period, Abbott Point of Care Inc. shall, at its option, either repair or replace products which prove to be defective. With respect to software or firmware, if Abbott Point of Care Inc. receives notice of defects in these products during the warranty period, Abbott Point of Care Inc. shall repair or replace software media and firmware which does not execute their programming instructions due to such defects. Abbott Point of Care Inc. does not warrant that the operating of the software, firmware or hardware shall be uninterrupted or error free. If Abbott Point of Care Inc. is unable, within a reasonable time, to repair or replace any product to a condition as warranted, Buyer shall be entitled to a refund of the purchase price upon return of the product to Abbott Point of Care Inc.

The warranty for the 9V rechargeable battery remains in effect for one year following the Born on Date (BOD) noted on the battery's label (pictured below).

Note: Warranty rights may vary from state to state, province to province and country to country.

Limitations of Warranty

The foregoing warranty shall not apply to defects resulting from:

1   Improper or inadequate maintenance by Buyer or an unauthorized person,

2   Using accessories and/or consumables that are not approved by Abbott Point of Care Inc.,

3   Buyer-supplied software or interfacing,

4   Unauthorized repairs, modifications, misuse, or damage caused by disposable batteries, or rechargeable batteries not supplied by Abbott Point of Care Inc..

5   Operating outside of the environmental specifications of the product, or

6   Improper site preparation or maintenance.

THE WARRANTY SET FORTH ABOVE IS EXCLUSIVE AND NO OTHER WARRANTY, WHETHER WRITTEN OR ORAL, IS EXPRESSED OR IMPLIED. ABBOTT SPECIFICALLY DISCLAIMS THE IMPLIED WARRANTIES OR MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.

INTRODUCTION

The i-STAT 1 Analyzer is used in conjunction with i-STAT cartridges for the simultaneous quantitative determination of specific analytes in whole blood.

Refer to the Cartridge and Test Information section of this manual for information on analytes that can be measured using i-STAT cartridges.

BEFORE YOU USE THE ANALYZER

Install Batteries See the Care of the Analyzer section in this manual for the procedure to install the disposable batteries. If a rechargeable battery is to be used, the disposable batteries can be used while the rechargeable battery pack is charged in the Downloader/Recharger. Charge rechargeable batteries fully before use. See the i-STAT 1 Downloader section for this procedure. When using a rechargeable battery, store the disposable battery carrier for possible future use.

Check Date and Time Press the On/Off key and check that the date and time at the top of the display are correct. To change the date and time, see Administration Menu in this section.

Check Software **Caution**: New analyzers or analyzers that have been repaired and returned or replaced will have standard CLEW and application software. If a different CLEW and/or application software is in use in your facility, it must be installed in new, repaired or replaced analyzers before they are put into use. Check the Analyzer Status page for the installed CLEW and application software. See under "Standardization and Calibration" in section 3 of this manual for an explanation of CLEW.

Customization Analyzers can be customized for many site-specific testing requirements. See the Customization section for a list of customizable parameters and their default values. To change the customization profile via the analyzer keypad see "Customization" under "Administration" in this section of the manual. To change the customization profile via the Central Data Station, see the "Customization Workspace" in the Central Data section of this manual.

Caution: New analyzers or analyzers that have been repaired and returned or replaced will have the factory default settings in the customization profile, as indicated by the DEFAULT0 on the Analyzer Status page. If analyzers in your facility do not use the default customization profile, the appropriate customization profile should be installed before a new, repaired or replaced analyzer is put into use.

Perform Quality Check Use the Electronic Simulator to verify the cartridge-reading performance of new or repaired analyzers.

Use QC protocols to verify the test strip-reading performance of new or repaired analyzers.

DESCRIPTION

Specifications

DIMENSIONS	Width 7.68 cm (3.035 in.)
	Length 23.48 cm (9.245 in.)
	Depth 7.24 cm (2.85 in.)
WEIGHT	With rechargeable battery 650 grams (22.9 oz.)
	With disposable battery 635 grams (22.4 oz.)
POWER	Two 9-volt lithium batteries, or rechargeable battery.
CALIBRATION	Factory: electronic, mechanical, thermal, pressure
MEMORY/CLOCK BACKUP POWER	Lithium Battery
DISPLAY	Dot matrix supertwist liquid crystal
COMMUNICATION LINK	Infrared light-emitting diode (LED)
OPERATING TEMPERATURE	16-30°C (61-86°F) for i-STAT cartridge testing
TRANSPORT TEMPERATURE	-10-46°C (14-115°F)
RELATIVE HUMIDITY	90% (maximum) non-condensing
BAROMETRIC PRESSURE	300-850 mmHg
LASER SCANNER	Complies with U.S. 21 CFR 1040.10 and 1040.11 except for deviations pursuant to laser Notice No. 50, dated June 24, 2007.
	EN 60825-1:1994 + A1:2002 + A2:2001
	IEC 60825-1:1993 + A1:1997 + A2:2001

Software

All analyzer functions are controlled by application software that can be updated as additional tests and features are developed. Coefficients used to maintain the accuracy of cartridge results over time are programmed into the analyzer via CLEW software updates every six months. See under "Standardization and Calibration" in section 3 of this manual for an explanation of CLEW.

Power

There are two power options for the analyzer: disposable and rechargeable. The analyzer is shipped with a batter carrier for use with two disposable 9-volt lithium batteries. Lithium batteries may be ordered from i-STAT or obtained locally. ULTRALIFE® lithium batteries (ULTRALIFE Batteries, Inc., Newark, NY, USA) are recommended. Only i-STAT rechargeable batteries may be used.

Battery Compartment

The battery compartment is located at the display end of the analyzer next to the laser barcode scanner window. The procedure for changing disposable and rechargeable batteries can be found in the Routine Care of the Analyzer and Downloader section of this manual.

Art: 714364-00O   Rev. Date: 26-Feb-16

Disposable Batteries   The analyzer requires two 9-volt lithium batteries. The lifetime for a set of batteries is mainly dependent on the mix of cartridges in use. Cartridges that require thermal control consume more energy because of heating. Coagulation and immunoassay cartridges consume more energy because of the longer test cycle. A minimum of 400 thermally controlled cartridge uses, about 100 coagulation cartridges, or 50 immunoassay cartridges can be expected before replacement is necessary. Backlighting, if used continuously, may reduce battery life up to 50%. Extensive laser scanning will affect battery life slightly.

The lithium batteries should be removed from the analyzer when long periods, such as six months, of no use are anticipated.

Rechargeable Battery   The analyzer can be powered by a nickel-metal-hydride rechargeable battery. The battery capacity for one full charge is 30% (minimum) of the capacity of one set of disposable lithium batteries (see above). If the analyzer is not in use, batteries will lose approximately 10-30% of their charge over 30 days if not recharged.

Store rechargeable batteries in a cool dry place when not in use.

The battery recharges when the analyzer is placed in a Downloader/Recharger. The battery pack can be removed from the analyzer and placed in the separate recharging compartment on the Downloader/Recharger. Full recharge from a discharged state takes approximately 40 hours. The analyzer will display "Low Battery" when battery recharge is needed.

Caution: Do not short circuit, incinerate or mutilate the recharegable batteries.

Low Battery Warning   The analyzer will display "Low Battery" when the On/Off key is pressed. Additionally, a flashing battery icon will display on the results screens, as well as the Test Menu and Administration Menu screens when battery replacement is needed. Data is not lost when batteries are fully discharged.

Additional Power   A lithium battery inside the analyzer maintains the clock/calendar and customization profile. This battery should last seven years.

Cartridge Port   Cartridges and the Electronic Simulator are inserted into the analyzer through the cartridge port on the keypad end of the analyzer. Unless the analyzer is customized to require information input before a test, inserting a cartridge or Electronic Simulator initiates the test cycle (i.e., the analyzer does not need to be turned on first).
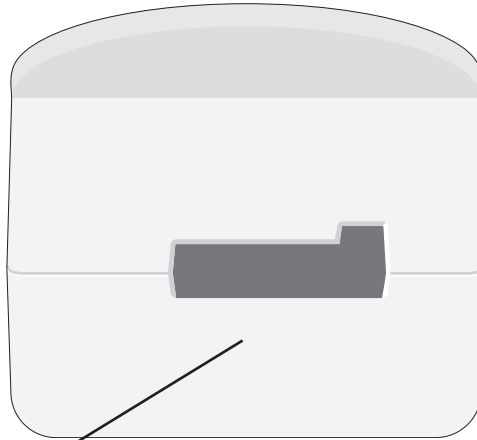
i-STAT Cartridge Port

Infrared Communication
Window

Battery Compartment   Laser Barcode Scanner
Window
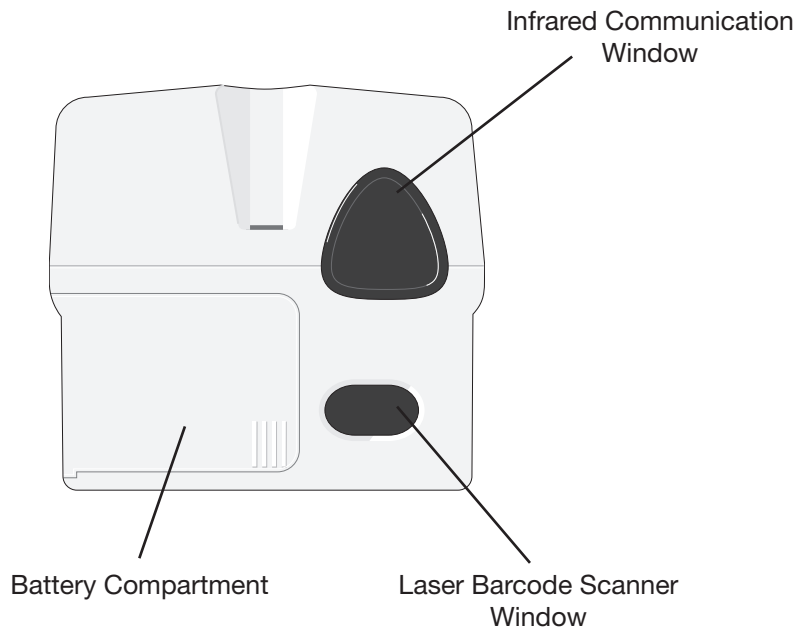
Infrared Communication Window	The Infrared Communication Window provides the analyzer with two-way communication to the Central Data Station via a Downloader, allows analyzer-to-analyzer software updates, and allows analyzer-to-printer communication for printing.
Thermal Control	The analyzer contains a thermal control subsystem of thermistors and heating contact wires that controls the temperature of the sensors and fluids that come into contact with the sensors to 37°C. This subsystem is activated automatically when a cartridge containing tests which require thermal control at 37°C is inserted into the analyzer.
Barometric Pressure Sensor	The analyzer contains a solid-state barometric pressure sensor, which determines the ambient atmospheric pressure used for the PO_2 sensor calibration.
Cartridge Test Cycle	An operator starts a cartridge test cycle either by inserting a cartridge into the analyzer or by selecting the i-STAT Cartridge option from the Test or Quality Tests Menu.

The analyzer:

- makes electrical contact with the cartridge
- identifies the cartridge type
- releases calibration fluid to the sensors (when applicable)
- mixes sample and reagent (when applicable)
- measures barometric pressure
- heats the sensors to 37°C (when required by the test)
- measures electrical signals generated by the sensors and calibration fluid (when applicable)
- displaces the calibrant solution with sample (when applicable)
- measures electrical signals generated by the sensors and sample
- accepts the operator and patient IDs scanned or entered by the operator
- accepts chart page information
- calculates and displays results
- stores results

Data Entry

Data that can be scanned into the analyzer or entered via the keypad include:

- Operator ID
- Patient ID, Proficiency ID, or Simulator ID
- Cartridge Lot Number
- Control Lot Number
- Cal Ver Kit Lot Number
- Comment codes for patient and control results
- Chart Page
    - Sample Type
    - Patient Temperature - The analyzer will interpret numbers between 50.0 and 110.0 as degrees Fahrenheit and between 10.0 and 45.0 as degrees centigrade. When a patient temperature is entered, blood gas results will be displayed at both 37°C and the patient's temperature.
    - FIO2
    - Free Fields: three fields, up to 9 characters each

```
           Pt:145
_____
Scan or Enter Data
Sample Type
Field 1 _ _ _ _ _ _ _ _ _
Field 2 _ _ _ _ _ _ _ _ _
Field 3 _ _ _ _ _ _ _ _ _
PtTemp  _ _ _ _ _
FIO2    _ _ _
CPB              No

  1-ART      4-CAP

  2-VEN      5-CORD

  3-MIX      6-OTHR
        ➡ Page
    Results Ready
```

See the Customization section in this manual for barcode formats recognized by the analyzer.

Storage of Results

The analyzer automatically stores up to 1,000 test records. A test record consists of:

- a set of results
- the date and time the test was performed
- the cartridge type
- all information entered by barcode scanner or keypad including:
    - Operator and Patient IDs
    - Lot numbers for controls and cartridges
    - Chart page data
    - Serial number of the Electronic Simulator
- the serial number of the analyzer
- the number of times the analyzer has been used
- the software and CLEW versions installed in the analyzer
- the name of the analyzer's customization profile

Quality Check Codes, which may appear during the test cycle indicating a problem with the sample, calibration, sensors, mechanical or electrical functions of the analyzer, are also stored.

The Analyzer Status option under the Administration Menu lists the number of stored records as "Total" and "Unsent" records. Test records are stored as "Unsent" until the analyzer uploads data to the Central Data Station at which time the records are marked as sent. The analyzer can be customized to display a Memory Full prompt or to disable testing until data is transmitted to the Central Data Station. Otherwise, the oldest data is overwritten when the memory becomes full. Stored test records can be reviewed through the Data Review option on the Administration Menu screen described later in this section.

Art: 714364-00O

LCD Display and Backlight

Test results, operator prompts and other messages are displayed on the analyzer's LCD Screen. The backlight for the display is turned on and off by pressing the 0 key for one second. The backlight will automatically turn off after ninety seconds and when the analyzer powers down or is turned off. The backlight cannot be turned on while data entry screens are displayed.

Audible Indicator

The analyzer will beep to indicate:

- whenever a key is pressed.
- a successful barcode entry.
- results are ready.
- a Quality Check Message is displayed.

The analyzer can be customized to disable beeping when a key is pressed or results or messages are displayed.

```
      Code # 31
    17:42 30JUN00

      UNABLE TO
       POSITION
        SAMPLE

      USE ANOTHER
       CARTRIDGE


    1- Test Options
```
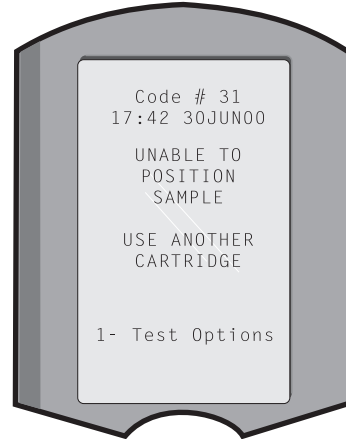
Time Out

The analyzer automatically turns off after a certain period of inactivity.

- **Results displayed:** Results are displayed for 2 minutes before the analyzer turns off provided that a mandatory Comment Code prompt is not displayed. This Inactivity Time Out default time can be increased using Customization.

  If a mandatory Comment Code prompt is displayed, the analyzer will turn off after 15 minutes or after the Inactivity Time Out, whichever is greater. In the case of a missed required Comment Code, results will be stored and "_ _ _" will be entered as the Comment Code.

- **Prompting for mandatory data when results are ready for display:** The analyzer will turn off after 15 minutes or after the Inactivity Time Out, whichever is greater, if there is no response to a mandatory data prompt. A mandatory data prompt is a prompt for information that must be entered before pending results are displayed.

  In the case of a missed mandatory data prompt, results will not be stored and the test record will state "Test Cancelled by Operator."

- **Waiting for insertion of cartridge:** After the prompt "Insert Cartridge" is displayed, the analyzer will wait 15 minutes for the operator to insert a cartridge unless the analyzer is in the Proficiency path, in which case the analyzer will wait 5 minutes. If a cartridge is not inserted, the analyzer will turn off. This timeout cannot be customized.

- **Other:** The analyzer will turn off after 2 minutes of inactivity (no keys pressed) in all other circumstances.

Keypad

There are 19 keys located directly below the display. When using the keypad to enter information, the number of dashes in the data entry line will indicate how many characters can be entered on the line. The dash where the next entry will be placed will flash.

Key	Function
SCAN	Activates the barcode scanner. Information that can be entered into the analyzer via the scanner includes: operator ID, patient ID, control and cartridge lot number, patient chart data and comment codes.
← →	Used to move the cursor on the Set Clock screen and to move up and down the alphabet when the ABC key is pressed. The ➡ (right arrow) key is used as a page key to move from one screen to the next. When Patient ID Recall is enabled, the ➡ key will recall the last patient ID when the analyzer is prompting for Patient ID. The ⬅ (left arrow) key is used to backspace and clear keypad entries, and to move backward through the screens within a menu.
ABC	Used to enter alpha characters on data entry screens. When the ABC key is pressed the letter A is entered. The arrow keys are used to move up and down the alphabet. To enter a second letter, press the ABC key once to move to the next position and again to enter an A. To enter a number after a letter, press a numbered key. To erase a letter, press the ABC key to move to the next position, then use the ⬅ key to backspace and clear the letter.
0 – 9	Used to enter digits on data entry screens and to select menu options and stored records.
•	Enters a decimal point or a comma separator according to the analyzer's Customization Profile.
☼0☼	Used to turn the screen backlight on and off.
Enter ENT	Used to respond to a prompt to complete an action, such as entering an operator or patient ID via the keypad.
MENU	Used to return to the previous menu and switch between the Test and Administration Menus.
Print PRT	Used to print either directly to the portable printer or to the portable printer attached to a Downloader.
On/Off ⏻	Turns the analyzer on or off. When the analyzer is on, the On/Off key must be pressed for a second to turn the analyzer off. This key is inactive when a test is in progress and when the analyzer is prompting for mandatory data.

i-STAT 1 Menu Tree   There are two main menus: The Test Menu and the Administration Menu.

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Test Menu
1- Last Result
2- i-STAT Cartridge

Administration Menu			
1. Analyzer Status	Temp Pressure Battery Uses Serial CLEW Version Custom Stored Records Total Unsent		
2- Data Review	1-Patient 2-Control 3-Proficiency 4-Cal Ver 5- Simulator 6- All 7- List		
3-Quality Tests	1-Control 2- Proficiency 3- Cal Ver 4- Simulator		
4- Customization	1-View	1- Analyzer 2- ID Entry 3- Patient Tests 4- QC Tests 5- Results	
	2-Change	1- Analyzer 2- ID Entry 3- Patient Tests 4- QC Tests 5- Results 6- Password 7- Restore Factory Settings	
5- Set Clock			
6- Transmit Data	1- Most Recent 2- This Month 3- Last Month 4- All 5- Unsent		
7-Utility	1- Send Software 2- Clear Memory 3- Receive Software		

TEST MENU

The Test Menu is displayed when the analyzer is turned on using the On/Off key.

The options are:

     1 - Last Result

     2 - i-STAT Cartridge

Option 2 is used for testing patient samples.

Note: If the handheld is customized to disable testing under certain conditions, the disabled option will be listed without its number so that it cannot be selected.

```
 15:26 30JUN00
   Test Menu

1- Last Result
2- i-STAT Cartridge
```

```
 15:44 30JUN00
   Test Menu

1- Last Result
 - i-STAT Cartridge


 Upload Required
 Testing Disabled
```
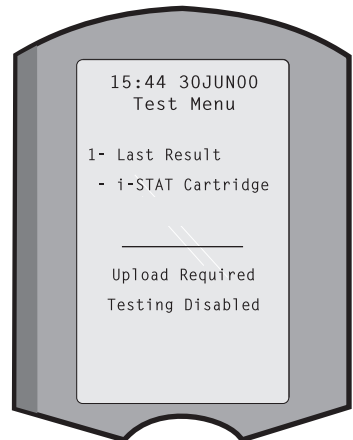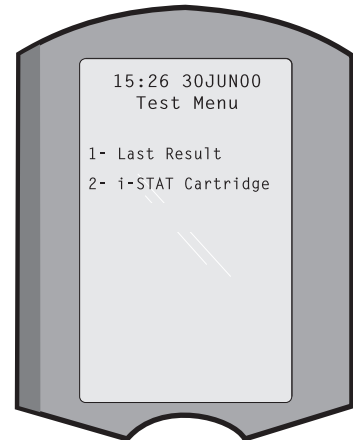
ADMINISTRATION MENU

Overview

The Administration Menu is accessed by pressing the Menu key from the Test Menu screen. The options are:

     1 - Analyzer Status

     2 - Data Review

     3 - Quality Tests

     4 - Customization

     5 - Set Clock

     6 - Transmit Data

     7 - Utility

```
  13:22 21JUN00
Administration Menu

1- Analyzer Status
2- Data Review
3- Quality Tests
4- Customization
5- Set Clock
6- Transmit Data
7- Utility
```
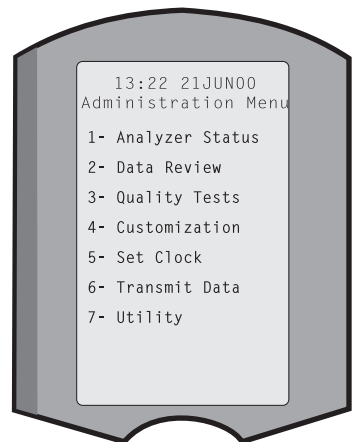
Analyzer Status

The Analyzer Status screen contains information about the condition or "status" of the analyzer. Fresh readings are made whenever this option is selected.

Temp	Room temperature.
Pressure	Barometric pressure.
Battery	Battery voltage.
Uses	Total number of cartridge and simulator test cycles, whether or not results reported.
Serial	Serial number of the analyzer.
CLEW	Version of standardization data installed in the analyzer.
Version	Version of application software installed in the analyzer.
Custom	Customization profile name.
Stored Records	Total: The number of test records in the analyzer's memory. The maximum storage capacity is 1,000 test records, which include records with results and Quality Check Codes for patients and controls both liquid and electronic.
	Unsent: The number of test records that have not been transmitted to the Central Data Station.

```
   Analyzer Status
Temp: 23.9C
Pressure: 760mmHg
Battery:  8.20V
Uses: 118
Serial: 300102-A
CLEW: A82
Custom: Default1
Version: JAMS108

   Stored Records
Total: 116
Unsent: 22
```
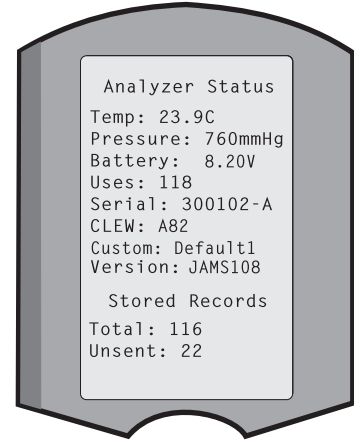
Data Review

The Data Review function allows the operator to review stored results by the categories listed below. The number of test records stored is indicated at the bottom center of the screen as x/y where x is the record on the screen and y is the total number of stored records in the selected category. The 1 and 2 keys are used to scroll through the stored records as indicated on the bottom right and left of the screen. The most recent test record is always in the first position. The right arrow key is used to page through the screens of the displayed record.

1 - Patient The records for a patient are recalled by scanning or entering via the keypad the Patient ID. If no Patient ID is entered, all patient tests are recalled.

2 - Control

3 - Proficiency

4 - Cal Ver

```
   Data Review

 1- Patient
 2- Control
 3- Proficiency
 4- Cal Ver
 5- Simulator
 6- All
 7- List
```

5 - Simulator All external and internal Electronic Simulator records.

6 - All All test records in the analyzer's memory.
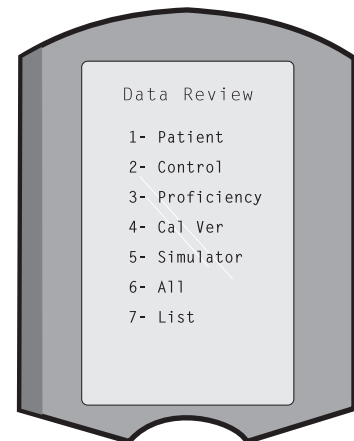
7 - List   Records are listed with
                    Cartridge type, date and time
                    of test, patient ID, control lot,
                    proficiency ID, or Cal Ver lot
                    and test level as applicable.
                    Any number of test records
                    can be selected for viewing
                    or printing using the number
                    keys. Pressing the number
                    key corresponding to a record
                    selects a record; pressing the
                    number key a second time
                    deselects the record.

```
   Select Records To
    Review or Print

 1  i-STAT G3+
    09:25 20JUN00
    02439790
 2  i-STAT EG7+
    09:05 20JUN00
    02439790
 3  Simulator
    08:15 20JUN00
    Pass




    ← Page →
```

To view one or more records,
select the records and press
the Enter key. To print records,
select the records and press the Print key.
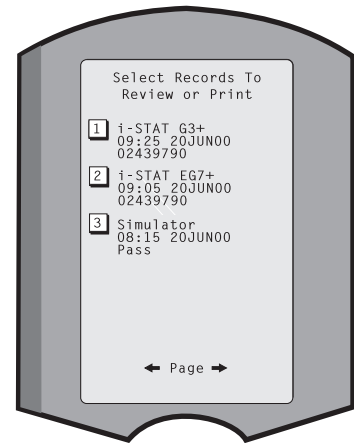
Quality Tests

Non patient tests can be initiated from the Quality Tests menu. Options are:

1 - Control

2 - Proficiency   (external quality control)

3 - Cal Ver   (Calibration Verification for cartridges)

4 - Simulator   (cartridge-reading function only)

```
   Quality Tests

 1- Control

 2- Proficiency

 3- Cal Ver

 4- Simulator
```

When testing is initiated from one of these options, the handheld prompts the operator to scan or enter the Operator ID; the Control Lot Number, Proficiency ID, Cal Ver Kit Lot Number, or Simulator ID as applicable; and the Cartridge Lot Number.

When the Quality Tests option is used, results can be reviewed according to the corresponding options under the Data Review option.

Customization Analyzers can be customized for site-specific testing characteristics and requirements. A complete list of customizable parameters and their default values can be found in the Customization section. An analyzer can be customized via the keypad or via the Central Data Station. Items that cannot be customized via the analyzer's keypad are operator lists, test strip lists, reference and action ranges, sample types and order of items on the Chart page.

The Central Data Station's Customization function can be used to create one customization profile for all analyzers or different profiles for different locations. When the Customization function is enabled, the profiles are transmitted to the analyzers when they are placed in a Downloader.

Caution: If location specific customization profiles are created, analyzers should not be moved from one location to another unless they are re-customized for the new location. This is especially important if "CPB: Automatically Adjust" or "CPB: Do Not Adjust" is included in a location-based customization profile. The CPB function adjusts hematocrit and hemoglobin results for the dilutional affect of pump fluid during cardiopulmonary bypass surgery. If an analyzer customized for the CVOR as "CPB: Automatically Adjust" is used for patients who are not on the pump, hematocrit results will be reported falsely high. If an analyzer customized as "CPB: Do Not Adjust" is used for patients who are on the pump, hematocrit results will be reported falsely low. For details on the CPB function, see the Theory section of this manual.

It is recommended that only one method, the Central Data Station or the keypad, be used to customize all analyzers within a site. If both methods are in use, and the Customization function is not disabled on the Central Data Station, any changes made to the profile of an analyzer via the keypad will be overwritten the next time the analyzer is placed in a Downloader.

The customization profile of an analyzer is identified in the Customization option under the Administration Menu on the analyzer. DEFAULT0 indicates that the analyzer has factory settings. When an analyzer has been customized via the Central Data Station (CDS), the name assigned to the profile by the CDS is listed. If the default or CDS profile is changed on the analyzer, the profile is listed as 00000000.

**Viewing the
Customization
Profile**

Select **4- Customization** from the Administration Menu, select **1- View** then select from the Customization Menu:

>   1 - Analyzer
>
>   2 - ID Entry
>
>   3 - Patient Tests
>
>   4 - QC Tests
>
>   5 - Results

Select a category to review. Use the ← and → keys to scroll through the preferences for each category and use the ← key to return to the Customization menu.

The Customization review option on the analyzer does not display the certified operator list or the valid test strip lot list. These items can be viewed on the Central Data Station.

Note:
  ○ Outside the USA, the following changes should be considered: language, unit set, date format and decimal separator.

     1 - Analyzer

> <u>First page</u>
> Date Format
> Sound
> Auto-transmit
> Memory Full
> Batch Mode Timeout
>
> <u>Second page</u>
> Inactivity Timeout
> Upload Schedule
> Clock Password
> Sync Clock
> Patient Record Limit Access
>
> <u>Third page</u>
> Wireless (only available with the i-STAT wireless analyzer)

      2 - ID Entry

        1 – Operator ID

> <u>First page</u>
> Minimum Length
> Maximum Length
> Repeat ID
> Manual Entry
> Code I2of5
>
> <u>Second page</u>
> Code 128
> EAN-8, EAN-13
> Codabar
> Code 93
> Code 39

Third page
Code 39 Check Digit
Truncate First
Truncate Last
Operator List
Not Certified Action
Not In List Action

Fourth page
Warn User
Print ID

2 – Patient ID

First page
Minimum Length
Maximum Length
Repeat ID
ID Recall
Manual Entry

Second page
Code I2of5
Code 128
EAN-8, EAN-13
Codabar
Code 93

Third page
Code 39
Code 39 Check Digit
Truncate First
Truncate Last
Patient List
Not in List Action

Fourth page
Lockout Override
Confirmation Method
Print ID

3 - Patient Tests

First page
Cartridge Auto-chart
Cartridge Information
Cartridge Barcode
Cartridge Lot Number
Comment Code In Range

Second page
Comment Code Out of Range
Cart Sample Type
Result Output
Downloader Lockout
STATNotes

4 - QC Tests
              1 – Simulator
                     Ext Simulator
                     Int Simulator
                     Int Simulator Schedule Option

              2 – Cartridge QC
                     First page
                     Pass/Fail Method
                     Comment Code In Range
                     Comment Code Out of Range
                     Result Format
                     APOC fluid Lot Scan Only
                     Second page
                     eVAS Name
       5 - Results
              1 – ACT/Ref Ranges
              2 – Display Ranges
              3 – Units

              4 – Options
              First page
              Decimal Separator
              Test Selection
              Hematocrit
              Base Excess
              ACT-C

              Second page
              ACT-K
              Print Ref. Ranges

Changing the Profile   To customize via the handheld keypad, select **4- Customization** from the Administration Menu, then select **2- Change**. If the handheld has already been customized with a password, enter the password. If not, press the Enter key. (It is recommended that the Change function be password protected). Then make selections from the Customization menu. To change a setting, select the item by pressing the number key correponding to the item, then select the setting. Use the → key to view all items. After all items have been set, turn the handheld off to save and activate the settings.

Note:

   ❍   Outside the USA, the following changes should be considered:
        language, unit set, date format and decimal separator.

       1 - Analyzer

              First page
              Language
              Date Format
              Sound
              Auto-transmit
              Memory Full

              Second page
              Batch Mode Timeout
              Inactivity Timeout
              Upload Schedule
              Clock Password
              Sync Clock

              Third page
              Wireless (available with the i-STAT 1 wireless)

2 - ID Entry

  1 – Operator ID

    <u>First page</u>
    Minimum Length
    Maximum Length
    Repeat ID
    Manual Entry
    Code I2of5

    <u>Second page</u>
    Code 128
    EAN-8, EAN-13
    Codabar
    Code 93
    Code 39

    <u>Third page</u>
    Code 39, Check Digit
    Truncate First
    Truncate Last
    Print ID

  2 – Patient ID

    <u>First page</u>
    Minimum Length
    Maximum Length
    Repeat ID
    ID Recall
    Manual Entry

    <u>Second page</u>
    Code I2of5
    Code 128
    EAN-8, EAN-13
    Codabar
    Code 93

    <u>Third page</u>
    Code 39
    Code 39 Check Digit
    Truncate First
    Truncate Last

3 - Patient Tests

    <u>First page</u>
    Cartridge Auto-chart
    Cartridge Information (functionality preset by analyzer firmware)
    Cartridge Barcode (functionality preset by analyzer firmware)
    Cartridge Lot Number (functionality preset by analyzer firmware)
    Comment Code, In Range

    <u>Second page</u>
    Comment Code, Out of Range
    Result Output
    Downloader Lockout

4 - QC Tests

  1 – Simulator

    Ext Simulator
    Int Simulator
    Int Simulator Schedule Option

2 – Cartridge QC
   Pass/Fail Method
   Comment Code In Range
   Comment Code Out of Range
   Result Format
   APOC Fluid Lot Scan Only

5 - Results
 1 – Units and Ranges
 2 – Options
   <u>First page</u>
   Decimal Separator
   Test Selection
   Hematocrit
   Base Excess
   ACT-C
   <u>Second page</u>
   ACT-K
   Print Ref. Ranges

6 - Password

7 - Restore Factory Settings

Set Clock

If the analyzer is customized with a password, the Set Clock function will be password protected. If a password has not been assigned, pressing the Enter key will display the time and date screen. Use the arrow keys to move the cursor to the digit to be changed. Use a number key to change the digit. Press Enter to accept the changes or Menu to cancel the changes. An invalid entry, such as 13 for a month, will not be accepted.

```
Enter Current
Time And Date

   13:40
  06/21/00
  mm/dd/yy


ENTER-Set And Exit
 MENU-Cancel
```

The format of the date on this screen can be customized using the Central Data Station Customization function, as mm/dd/yy or dd/mm/yy. The analyzer recognizes years in which February has 29 days.

The analyzer can be customized using the Central Data Station to synchronize or update the real time clock to the Central Data Station's clock at the time of each download. This option eliminates the need to reset the analyzer's clock at the beginning and end of Daylight Saving Time. Otherwise, the clock must be manually changed for Daylight Savings Time changes.
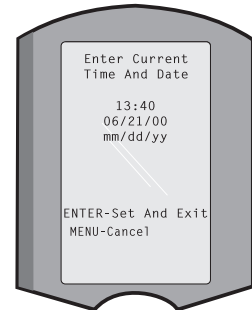
Transmit Data

Unsent test records are automatically transmitted to the Central Data Station when an analyzer is placed in a Downloader or Downloader/Recharger. In some cases it may be desirable to have the capability to retransmit data. The Transmit Data function allows transmission of data in the following manner:

1 – Most Recent

2 – This Month

3 – Last Month

4 – All

5 – Unsent

Most Recent is the result from the last cartridge tested.

```
Transmit Data

1- Most Recent
2- This Month
3- Last Month
4- All
5- Unsent
```

The analyzer can be customized using the Central Data Station to apply a date range limit to the Transmit All functions.

Auto-transmit is temporarily disabled when the Transmit Data option is selected to allow the user to control transmission of data.
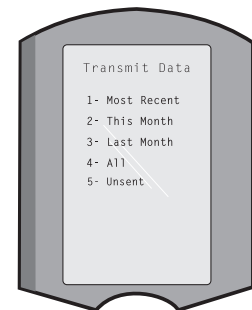
Utility

The Utility menu can be password protected using the Customization function on the analyzer or Central Data Station.

1 – Send Software: Allows the analyzer to transmit software to another analyzer. See the Software Update section of this manual.

2 – Clear Memory: Erases results from the analyzer's memory. Options are:

```
  Utility
Clear Memory

1- Previous To
   01Jun00
2- Previous To
   01May00
3- All
4- Cancel
```

1 – Previous to 01MMMYY (where MMMYY is current month and year, such as 01JUN00)

2 – Previous to 01mmmyy (where mmmyy is previous month and year, such as 01May00)

3 – All

4 – Cancel

3 – Receive Software: Allows users to remotely request a JAMS and CLEW update for the analyzer from the CDS. See section 18 (Updating Software) for full details.
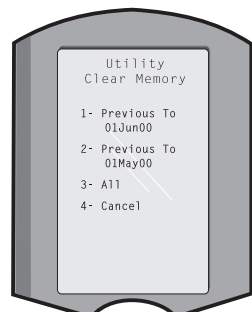
LASER BARCODE SCANNER

Laser Barcode Scanner

The barcode scanner is used to scan barcode information into the analyzer. Parameters that can be entered into the analyzer via the scanner include: operator and patient IDs, control and cartridge lot numbers, comment codes and patient chart data. The laser beam emerges from the recessed window on the front of the analyzer adjacent to the battery compartment. The laser beam automatically turns off after 3-4 seconds or after the barcode is successfully scanned.

Laser Specifications

The barcode scan engine is manufactured by Motorola Inc. or Opticon Inc. The scan engine contains a laser diode that emits laser radiation at a frequency of 650 nm. The scan engine outputs power (i.e., the power output of the engine if removed from this product) up to 1.9 mW in scanning mode. The scanner in this product only operates when the Scan key is pressed. The scan engine is intended to be used in a Class 2 device.

Warning Labels

Warning labels are shown below. The warning labels are located on the back or under-side of the analyzer, as shown. The location of the laser window from where the analyzer emits the laser beam is also shown below.

Laser Barcode Scanner Window

LASER RADIATION • DO NOT STARE INTO BEAM • CLASS 2 LASER PRODUCT
LASERSTRAHLUNG • NICHT IN DEN STRAHL BLICKEN • LASERGERÄT KLASSE 2
RAYONNEMENT LASER • NE PAS REGARDER LE FAISCEAU • PRODUIT LASER DE CLASSE 2
RADIACIÓN LÁSER • NO MIRAR EL RAYO DIRECTAMENTE • PRODUCTO LÁSER CLASE 2
RADIAZIONE LASER • NON GUARDARE IL RAGGIO • PRODOTTO LASER DI CLASSE 2
LASERSTRALING • NIET IN DE LASERSTRAAL KIJKEN • KLASSE 2 LASERPRODUCT
LASERSTRÅLNING • TITTA INTE IN I STRÅLEN • KLASS 2-LASERPRODUKT
RADIAÇÃO LASER • NÃO OLHAR FIXAMENTE PARA O FEIXE • PRODUTO LASER DE CLASSE 2
ΑΚΤΙΝΟΒΟΛΙΑ ΛΕΪΖΕΡ • ΜΗΝ ΚΟΙΤΑΖΕΤΕ ΤΗΝ ΑΚΤΙΝΑ • ΠΡΟΪΟΝ ΛΕΪΖΕΡ ΤΑΞΗΣ 2
LASERSTRÅLING • KIG IKKE IND I LASERSTRÅLEN • LASERPRODUKT AF KLASSE 2
LASERSÄTEILY • ÄLÄ KATSO SUORAAN SÄTEESEEN • 2-LUOKAN LASERLAITE
LASERSTRÅLING • IKKE SE INN I STRÅLEN • KLASSE 2 LASERPRODUKT
レーザー放射・光線を見つめないでください・クラス 2 レーザー製品
레이저 방사・광선을 똑바로 쳐다보지 마십시오・등급 2 레이저 제품

650 nm
LASER DIODE / LASERDIODE/ DIODE LASER / DIODO LÁSER / DIODO LASER / LASERDIOD /
DÍODO LASER / ΔΙΟΔΟΣ ΛΕΪΖΕΡ / LASERDIODI / レーザーダイオード / 레이저 다이오드

1.0 mW
MAX OUTPUT / HÖCHSTLEISTUNG / PUISSANCE MAXIMALE / EMISIÓN MÀX / EMISSIONE MAX /
MAXIMALE UITGANGSSPANNING / MAX UTEFFEKT / SAÍDA MÀX / MEГ. ΕΞΟΔΟΣ / MAKS. EFFEKT /
MAKS. ULOSTULO / 最大出力 / 최대 출력

Complies with 21CFR1040.10 and 1040.11 except for deviations
pursuant to Laser Notice No. 50, dated June 24, 2007
EN60825-1:1994 + A1:2002 + A2:2001
IEC60825-1:1993 + A1:1997 + A2:2001

i-STAT®1 Analyzer
MN: 300
Abbott Point of Care Inc.
104 Windsor Center Drive
East Windsor, NJ 08520 USA
Product of USA

Art: 714364-00O

Rev. Date: 26-Feb-16

Caution	**Do not open the analyzer.** The analyzer may only be opened by factory authorized service personnel. **Class 2 laser radiation when open; DO NOT stare into the laser aperture or the laser beam, or point the laser beam at other persons.**

Use of controls, adjustments or performance of procedures other than those specified herein may result in hazardous laser radiation exposure.

Class 2 laser scanners use a low power, visible light diode. As with any bright light source, such as the sun, the user should avoid staring directly into the laser beam. Momentary exposure to a Class 2 laser is not known to be harmful.

Barcode Label Quality

To ensure that printed barcode labels are reliably read by i-STAT handhelds, the best available printing methods and settings should be used. However, as specified in the *Health Industry Bar Code (HIBC) Provider Applications Standard* (ANSI/HIBC 1.3-2010), the quality of printed labels should meet the minimum grade level of 1.5.

Procedure

Before scanning, check to see what information is required by the displayed prompt. Hold the analyzer 3-12 inches (2.5 – 30.5 cm) from the barcode to be scanned. An angle of about 10 degrees from perpendicular is best. Hold the analyzer and place the object to be scanned on a flat surface or, place the analyzer on a flat surface and hold the object in front of the analyzer. Avoid accidentally scanning other nearby items. Avoid pointing the beam into anyone's eyes.

STEP	ACTION
1	Press and hold down the Scan key to start the barcode scanner. The analyzer emits a visible red beam.
2	Position the analyzer and barcode so the beam forms a red line that spans the entire barcode. Increasing distance between the barcode and analyzer lengthens the red line. The analyzer does not need to touch the barcode.
3	When the analyzer accepts the barcode, it will beep in acknowledgement and automatically turn off the beam. The beam will also turn off after 3-4 seconds.
4	View the data that was scanned by the analyzer and verify that it is correct.
5	Release the Scan key.
Note:	If the Scan key is released as soon as the beep is heard, the next prompt will be displayed and the information scanned will not be able to be viewed.

PROMPTS AND MESSAGES

Prompts

Either before or during the testing cycle, the analyzer will display prompts that require an operator action or keypad entry, such as "Enter Operator ID." Prompts are described in the manual when used. Some prompts require input before results are displayed. Prompts for the following information are mandatory:

- Operator ID
- Patient ID
- Lot Numbers for Quality Tests
- Cartridge Lot Number

Startup Messages

When the On/Off key is pressed the analyzer may display one or more startup messages. A startup warning message indicates an action that should be taken in the near future to maintain the analyzer in working condition. If the analyzer is customized to disable testing under certain conditions, a startup lockout message indicates the action that must be taken before testing is re-enabled.

Quality Check Messages

If the analyzer detects a problem during power on, a Quality Check message will be displayed indicating the action that must be taken before testing can begin.

A Quality Check message will also be displayed and testing halted if the analyzer detects a problem during the test cycle.

Startup messages and Quality Check messages are described in the Troubleshooting section of this manual. "Upload Required, Testing Disabled" is an example of a startup lockout message, "Battery Low " is an example of a startup warning message, and "Unable to Position Sample" is an example of a quality check failure during the testing cycle.

Note: The "Cartridge Locked" or "Simulator Locked" prompt is always displayed when a cartridge or Electronic Simulator is inserted into the analyzer. Any attempt to remove a cartridge or Electronic Simulator before this prompt is removed from the screen may cause damage to the analyzer.

Contents
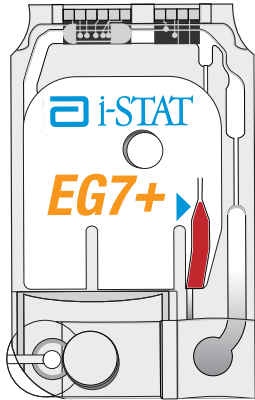
The unit-use disposable cartridge contains many of the subassemblies typically found in complex laboratory systems. Microfabricated thin film electrodes or sensors are assembled in unit-use cartridges containing:

- calibrant solution in cartridges with sensors for blood gases, electrolytes, chemistries and hematocrit
- analysis solution in immunoassay cartridges
- reagents in cartridges with sensors for coagulation
- sample handling system
- waste chamber
- an array of miniaturized sensors
- conductive pads to make electrical contact with the analyzer
- heating elements in cartridges requiring thermal control at 37 °C

See the Cartridge and Test Information Sheets for test-specific details.

The following diagram shows how a typical blood gas/chemistry cartridge is constructed.

Cartridge Label

Sample Entry Well Gasket

Fluid Channel

Cartridge Cover

Sample Entry Well

Tape Gasket

Biosensor Chips

Calibrant Pouch (if applicable)

Puncturing Barb

Cartridge Base

Air Bladder

Sample Handling System

Sensors *Contact Pads*

Sample Well
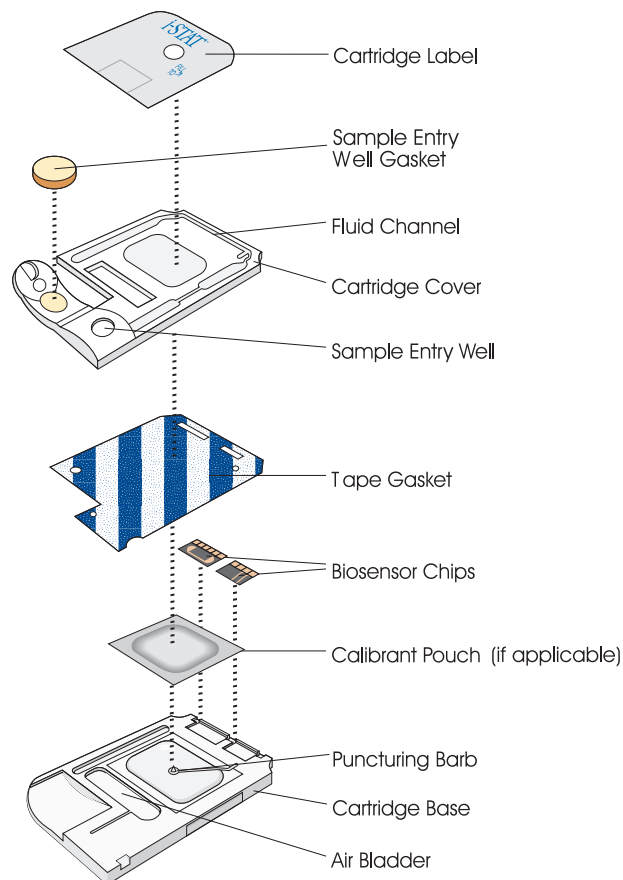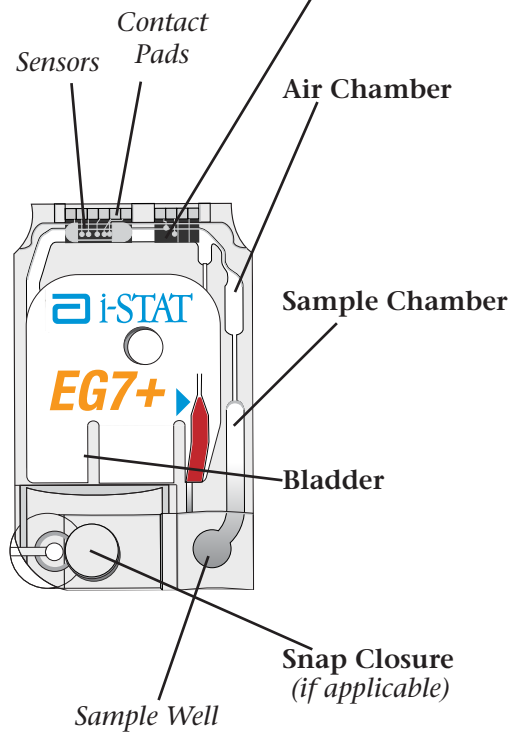
Part	Function
Sensor Channel	The sensor channel directs the sample from the sample chamber to the sensors. An extension of this channel becomes a waste chamber to receive the calibrant solution, if applicable, as it is displaced by the sample.
Air Chamber	An air chamber is located in blood gas/electrolyte/ chemistry/hematocrit cartridges between the sample chamber and sensor channel. This creates an air segment between the calibrant solution, if applicable, and the sample to prevent the two from mixing. The size of the air segment is monitored by the analyzer.
Sample Chamber	The sample chamber includes the sample well and the channel leading from the well up to the fill mark. When filled, the sample chamber contains sufficient sample for testing. Sample volume and placement are monitored by the analyzer.
Bladder	The bladder (concealed by the label) is connected to the sample well. The analyzer presses on the bladder to displace calibrant solution, if applicable, from the sensors to move the sample from the sample chamber to the sensors or to mix sample and reagents.
Snap Closure *(if applicable)*	The snap closure creates an airtight seal necessary for proper fluid movement within the cartridge. The closure also ensures that calibrant, if applicable, and sample remain contained within the cartridge during the testing cycle and subsequent disposal. Immunoassay cartridges, such as cTnI, use a plastic slide enclosure clip.
Air Vent	An air vent on the underside of the cartridge, beyond the fluid front, allows the calibrant and the sample to flow forward, but not out of the cartridge.
Waste Chamber	A waste chamber (beneath the cartridge label) holds calibrant fluid after it has been used.

Sensors

The sensors are electrodes microfabricated on silicon chips. Electrodes have chemically sensitive coatings such as ion-selective membranes and enzyme layers. In cartridges that perform coagulation tests, reagents, such as clot activators, are coated on the plastic above the sensors. Each sensor is connected to a contact pad by a signal line. The sensors respond to the calibrant solution, if applicable, and the sample by producing measurable signals related to analyte concentration. The performance characteristics for each sensor are described in the Cartridge and Test Information section. The section on theory describes the measurement principles.

Contact Pads

The contact pads conduct the signals generated by the sensors to the analyzer. In order to function properly, care must be exercised not to contaminate the contact pads during cartridge handling.

Heating Elements

All i-STAT cartridges require thermal control at 37 °C, and include heating elements on the underside of the sensor chips which are contacted and heated by the handheld's thermal probes.

Art: 714365-00H   Rev. Date: 11-Mar-14

Standardization and Calibration

Standardization is the process by which a manufacturer establishes "true" values for representative samples. The sensors in the i-STAT cartridges are standardized against plasma methods used by major laboratory systems or, for blood gases, against tonometry. A multi-point calibration curve, the slope or sensitivity of which is defined by coefficients in the CLEW software, is derived for each sensor by this standardization process. These calibration curves are stable over many lots and only need to be adjusted if a change in a manufacturing process affects the curve or if the relationship between results on the i-STAT System and other major laboratory systems drifts. For the convenience of users, CLEW updates are scheduled two times a year.

A one-point calibration is performed each time a cartridge requiring calibration is used. During the first part of the testing cycle, the calibrant solution is automatically released from its foil pack and is positioned over the sensors. The signals produced by the sensors' responses to the calibrant solution are measured. This one-point calibration adjusts the offset of the stored calibration curve. Next, the analyzer automatically moves the sample over the sensors and the signals produced by the sensors' responses to the sample are measured. While coefficients are used rather than graphic calibration curves, the calculation of the result is equivalent to reading the sample's concentration from adjusted calibration curve.

Packaging

Each cartridge is sealed in a foil pouch or clear plastic portion pack for protection during storage.

Labeling on the carton, box and pouch/portion pack identify:

- the panel name.
- the tests included in the panel.
- the lot number.
- the expiration date of the cartridge.

If the pouch/portion pack has been punctured, the cartridge should not be used.
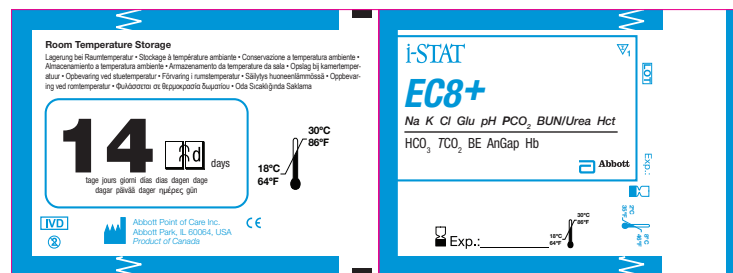
Storage Conditions   The main supply of cartridges should be stored at 2-8°C (35-46°F). Cartridges must be at room temperature before removing them from their pouches. Allow 5 minutes for an individual cartridge and one hour for a box of cartridges to come to room temperature. Cartridges in use may be stored at room temperature (18-30°C or 64-86°F) for the time frame indicated on the cartridge box. The cartridge box and pouch contain a line used to indicate the room temperature expiration date.

Disposal   Although the sample is contained in the cartridge, cartridges should be disposed of as biohazardous waste, according to local, state, and national regulatory guidelines.

Upon installation of the April 2012 Software Update, the Glucose Test Strip Port functionality will be permanently disabled on all i-STAT 1 Handhelds.

Note: The remaining technical information regarding the Glucose Strip Port will be removed from the i-STAT 1 System Manual by April, 2013. Please contact your Support Services representative for information on transitioning to an Abbott Diabetes Care blood glucose monitoring system.

ELECTRONIC SIMULATOR   5

Overview

The Electronic Simulator, external and internal, is a quality control device for the analyzer's cartridge signal-reading function. It simulates two levels of electrical signals that stress the analyzer's cartridge signal detection function both below and above measurement ranges.

While the analyzer performs internal electronic checks and calibration during each test cycle, the Electronic Simulator test provides an independent check on the ability of the analyzer to take accurate and sensitive measurements of voltage, current and resistance from the cartridge. An analyzer will pass or fail this electronic test depending on whether or not it measures these signals within limits specified in the analyzer software.

The schedule for the Electronice Simulator can be customized to meet local, state, or national accreditation requirements. A reminder message for the operator to run the external simulator can be set by the number of hours on the i-STAT Portable Clinical Analyzer and by the hours or tests on the i-STAT 1 Analyzer. The schedule for the automatic internal Electronic Simulator can be set by the number of hours on the i-STAT Portable Clinical Analyzer and by the hours or tests on the i-STAT 1 Analyzer. For details and lockout options, see the Customization section of this manual.

Note: All analyzers that pass the Electronic Simulator test are equivalent. Therefore, any representative number of analyzers that pass the Simulator test may be used for compliance with regulatory and accreditation quality assurance procedures. These procedures include initial performance verification studies, calibration verification, proficiency testing, and method comparison studies.

Relative Humidity

The Electronic Simulator test will fail if high humidity interferes with the measurements. Therefore it is not necessary to record humidity where the analyzers are in use.

Internal Simulator

When the specified time has elapsed since the last Electronic Simulator test (internal or external), the internal test will automatically be performed when a cartridge is inserted before the sample is tested, adding about 20 seconds to the testing cycle.

External Simulator

The external Electronic Simulator is a stable electronic device, which is inserted into the cartridge port. The test cycle for the external Electronic Simulator is about 60 seconds. (The test cycle for the internal simulator is shorter because it shares the initial part of the test cycle with the cartridge.)

Operating Characteristics

Operating Characteristics	
Dimensions	Height 1.9 cm Width 7.0 cm Length 9.0 cm
Weight	85 g
Operating Temperature	Same as Analyzer being tested
Operating Ambient Humidity	0-90% RH non-condensing (as shipped)
Storage Temperature	-20-50°C (-4-122°F)

Even when the internal Electronic Simulator is enabled, an external Electronic Simulator is needed:

- to validate an internal simulator failure.

- to reset the internal simulator schedule if a simulator test might interrupt testing, such as in a CVOR.

  Note: CVOR = Cardiovascular Operating Room

- for on-demand testing at any time.

- to perform the thermal probe check.

- to access the Proficiency and Calibration Verification test paths on the i-STAT Portable Clinical Analyzer.
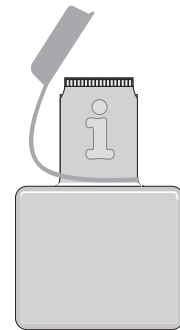
The external Electronic Simulator should be stored in the box in which it is shipped and the blue cap should be replaced after each use to protect the contact pads.

Stored Result   The results of the Simulator test are stored as a distinct record in the analyzer and can be transmitted to the Central Data Station.

Use ...   Use of the Electronic Simulator is described further in the Quality Control section of this manual.

Cleaning the Simulator   Before cleaning, cover the connector area with the blue rubber boot. This will minimize the possibility of any cleaning fluid getting into the simulator housing, thus contaminating the internal circuitry.

Clean the simulator with a gauze pad moistened with any of the cleaning agents approved for the analyzer, listed on page 17-1 of this manual.

Rinse the simulator using another gauze pad moistened with water and dry. DO NOT IMMERSE THE SIMULATOR IN ANY FLUID, AT ANY TIME.

If the connector itself is contaminated, the user should contact their Support Representative and arrange to have the simulator returned.

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Function

The Downloader converts infrared transmissions of test records from the analyzer to electrical form and transmits (uploads) them to the Data Manager. The Downloader also converts electrical signals from the Central Data Station to infrared transmissions, which are transmitted (downloaded) to the analyzer. Transmission is automatic when an analyzer is placed in a Downloader.

The Downloader comes in two formats:

 ✧ Downloader: A low-profile table-top unit with "arms" between which the analyzer is placed, and
 ✧ Downloader/Recharger (DR): a cradle that the analyzer is placed within.

Both Downloader formats are available for use with direct wiring (serial format) or ethernet cabling (network format). Unless indicated otherwise, references to the Downloader apply to the Downloader/Recharger as well.

The Downloader/Recharger can recharge a rechargeable battery in the analyzer. If the analyzer contains a rechargeable battery, the battery begins recharging automatically as soon as the analyzer is placed in the Downloader/Recharger. The Downloader/Recharger also has a compartment for recharging a rechargeable battery outside the analyzer.

Proximity Light   *Power Light*
Infrared Transceiver

i-STAT 1 DOWNLOADER

Proximity Light
Charging Light (battery in analyzer)
Infrared Transceiver

Recharging Compartment

Gold Charging Contacts

External Battery Pack Charging Light

i-STAT 1 DOWNLOADER/RECHARGER
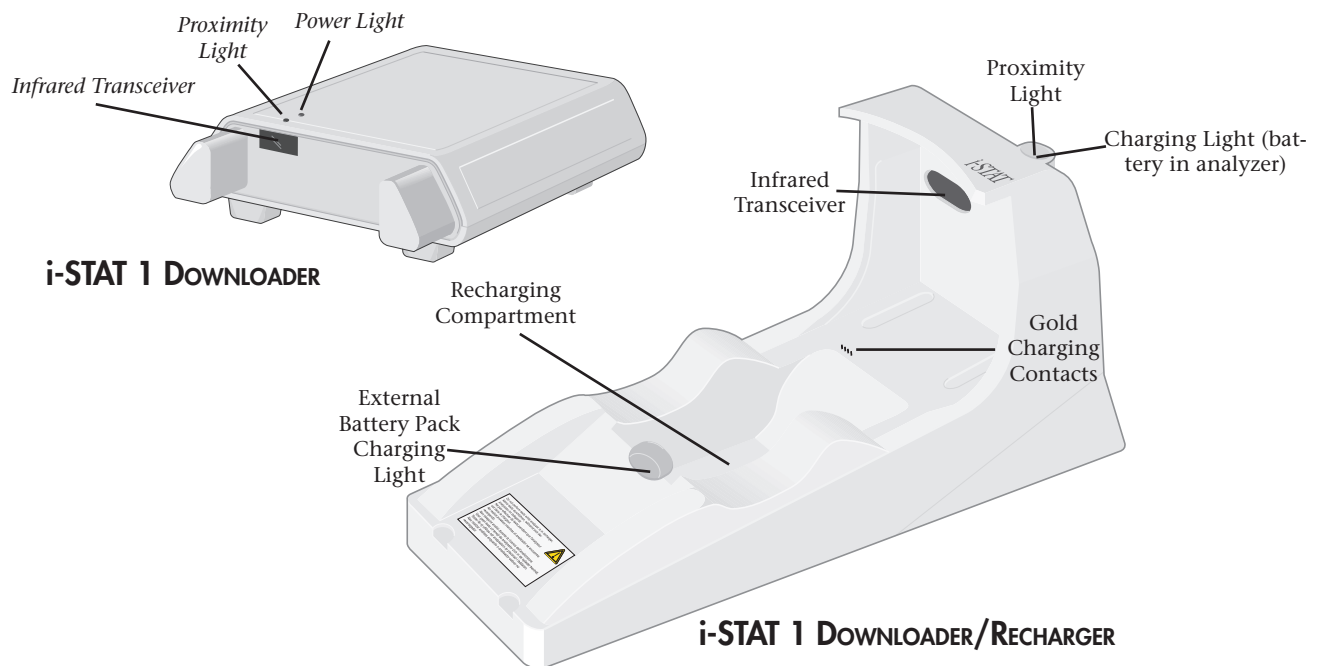
Specifications

Specification	Downloader	Downloader/Recharger
Size	5.25in (13.3cm) Wide 6.75in (17.2cm) Long 2.13in (5.4cm) High	4.12in (10.4cm) Wide 10.25in (26.cm) Long 5.00in (12.7cm) High
Weight	0.6 lbs (0.27kg)	1.2 lbs (0.55kg)
Power	AC-DC power adapter or PC/Downloader adapter. Input 12V ᴰᶜ	AC-DC power adapter or PC/Downloader adapter.* Input 12V ᴰᶜ
Operating Temperature	0 to 40˚C 32 to 104˚F	0 to 40˚C 32 to 104˚F
Storage Temperature	-20 to 50˚C -4 to 122˚F	-20 to 50˚C -4 to 122˚F
Pollution Degree (Allowable ambient pollution level)	2	2
Installation Category (Allowable overvoltage specification)	2	2
Communication To Central Data Station and other equipment	Serial (RS232), or Ethernet	Serial (RS232), or Ethernet
Communication Link To and From Analyzer	Infrared Transceiver	Infrared Transceiver
Indicator LEDs Power Proximity Charge	Green Red NA	NA Blue Red/Green
Configuration	By host computer	By host computer

Power Supply

Specification	Downloader and Downloader/Recharger
Input	100 - 240V~ 47 - 63 Hz .9 - .5A
Output	12V ᴰᶜ 3A max

* Recharge feature cannot be used in this configuration.

Running Cartridges in an Analyzer Docked in a Downloader/ Recharger

All i-STAT Cartridges may be run in Handhelds that are docked in a Downloader/ Recharger.

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Downloader/ Recharger Indicator LEDs

Analyzer Battery LED (near top of Downloader/Recharger)	
Off	No Rechargeable Battery
Blinking Red	Fast Charge Pending
Solid Red	Fast Charging
Solid Green	Trickle Charging
SPARE BATTERY (near middle of Downloader/Recharger)	
Off	No Rechargeable Battery
Green	Trickle Charging

Power Requirements

The Downloaders require one power outlet. The Downloader and Downloader/ Recharger must be used with the AC power supply adapter supplied with them. The Downloaders are capable of supplying power to the portable printer which reduces the number of power outlets required in the downloading and printing area.

DR Affect on Ambient Operating Temperature Range

The operating temperature for an i-STAT 1 Analyzer is 16°C to 30°C. The DR and Rechargeable Battery may raise the temperature of the i-STAT 1 Analyzer 2°C-3°C relative to the ambient temperature if:

- The Analyzer is frequently lifted and replaced into the DR

- Multiple thermally controlled cartridges are run in the Analyzer while it is in the DR.

Programming and Connections

Details for programming the Network Downloaders can be found in the Downloader Programming and Wiring section of this manual. Diagrams and instructions for connecting peripheral components to the Downloader can also be found in the Downloader Programming and Wiring section.

Cautions

The Downloader and Downloader/Recharger are not intended for use in the patient environment (within 1.5 meters of the physical location of the patient).

Users should not connect the Downloader or the Downloader/Recharger to a medical electrical system.

Do not place metal objects on or near the exposed gold charging contacts.

Be sure to install all cables and power supplies so they do not pose a trip hazard. Mount equipment so cables and accessories stay clear of walkways. The AC power supply adapter plug acts as the disconnect device for the Downloader and Downloader/Recharger and, therefore, the socket outlet must be installed (or located) near the Downloader or Downloader/Recharger and must be easily accessible.

Only i-STAT provided printers may be connected to the Downloader printer port.

An ethernet cable and serial (DB9) cable may <u>NOT</u> be connected to the Downloader at the same time.
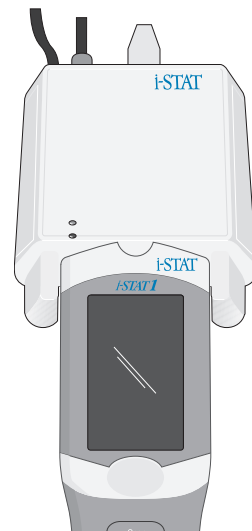
Transmitting Data from Downloader to the Data Manager

To transmit through a Downloader to the Data Manager, place the analyzer between the arms on the front of the Downloader with the test strip port end touching the Downloader. When properly aligned the red proximity light will turn on and the analyzer will automatically transmit (upload) all unsent results. (The analyzer does not need to be turned on.) Do not move the analyzer while the message "Communication in Progress" is displayed on the screen.

Transmitting Data from Downloader / Recharger to the Data Manager

To transmit data through a Downloader/Recharger, place the analyzer in the Downloader/Recharger's cradle. When properly aligned, the blue proximity light will turn on and the analyzer will automatically transmit (upload) all unsent results. (The analyzer does not need to be turned on.) Do not move the analyzer while the message "Communication in Progress" is displayed on the screen.
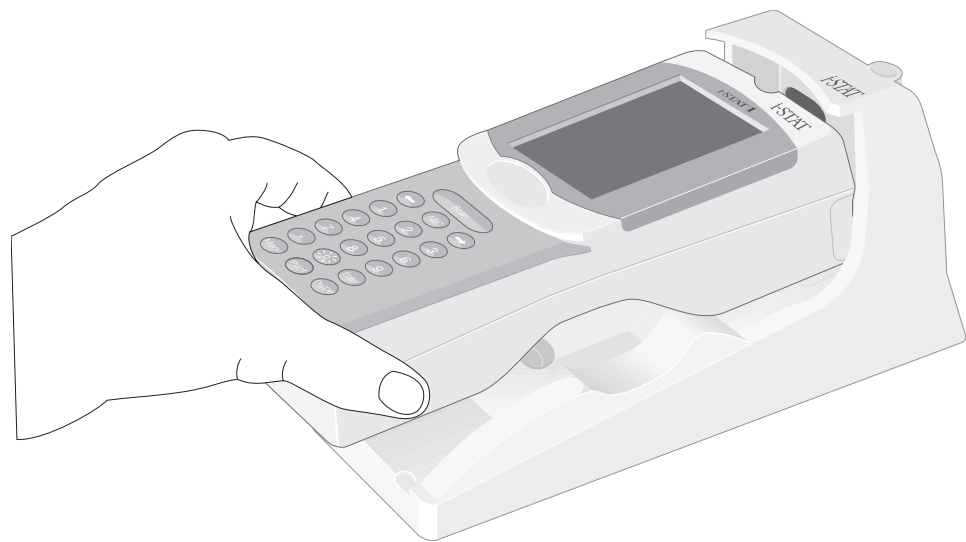
Transmitted Information

The following information is transmitted from the analyzer with each test record:

- ✧ The date and time the test was performed
- ✧ Operator ID and Patient ID or Quality Test fluid lot number
- ✧ All information entered by the operator, such as lot numbers, sample type and comment codes
- ✧ Result(s)
- ✧ Serial number of the analyzer
- ✧ Uses count of the analyzer
- ✧ Application software version in the analyzer
- ✧ Standardization software in the analyzer

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Troubleshooting
The analyzer displays "Waiting to Send" until communication is established with the Central Data Station. When communication is established the message changes to "Communication in Progress" and the arrows circle until upload is complete. If the message does not change from "Waiting to Send" or if the Analyzer Status screen reports unsent results after the upload, refer to Support Services in the Troubleshooting section.

```
       Waiting                    Communication
       To Send                     In Progress




        ↻                              ↻




      1 - Cancel                   1 - Cancel
```

Charge Battery Before Use
Put new rechargeable battery in external charging bay on the i-STAT®1 Downloader/Recharger for 40 hours. Battery will be 100% charged and ready for use. Analyzer with disposable batteries may be placed on Downloader/ Recharger to download data until rechargeable battery is ready.

Keep Battery Charged
Fully charged battery, if not periodically recharged, will self-discharge in approximately three months. Prevent self-discharge by either (1) keeping the rechargeable battery in an Analyzer that is periodically on the Downloader/ Recharger, or (2) store the rechargeable battery separately in the external charging bay on the Downloader/Recharger.

Charging the Rechargeable Battery
Placing an analyzer in a Downloader/Recharger will automatically initiate recharging of the rechargeable battery. The indicator light on top of the Downloader/Recharger will be green (trickle charge), red (fast charge), or blinking red (fast charge pending) when an analyzer with a rechargeable battery is placed in the Downloader/Recharger.

No damage will be caused if an analyzer with disposable batteries installed is placed in the Downloader/Recharger.

Charging Rechargeable Battery in External Recharge Compartment

Placing a rechargeable battery into the recharging compartment will automatically initiate trickle recharging. The indicator light near the recharging compartment will be green when a rechargeable battery is placed in the compartment.

STEP	ACTION
1	The battery pack has two labels: one for orientation in the analyzer and one for orientation in the Downloader/Recharger. With the label with the Downloader facing up and the electrical contact end of the pack facing the contacts in the battery compartment, insert the pack into the compartment as shown on the label.
2	To remove the battery after it is charged, back the pack out of the compartment.

Caution

Full recharge from a discharged state takes approximately 40 hours
If you are using rechargeable batteries, use only rechargeable batteries and recharging equipment supplied by your i-STAT distributor. Other batteries and rechargers may affect test results and pose other hazards to operators and patients. A falling instrument may cause injury. Place the instrument on a flat and stable surface at all times to ensure the instrument does not fall.
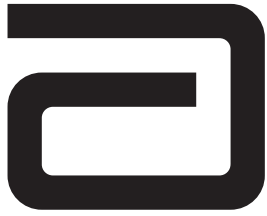
i-STAT®
TECHNICAL BULLETIN

THE i-STAT® 1 DOWNLOADER/RECHARGER (MODEL NUMBER DRC-300)

OVERVIEW

This Technical Bulletin describes the instructions for using the new i-STAT® 1 Downloader/Recharger (DRC), which is used to:

- convert infrared transmission signals from i-STAT 1 handheld test records to electrical form and transmit them via USB or network cabling to the Data Manager.

- convert electrical signals from the Customization Workspace of the Data Management application to infrared transmissions, and transmit them to the i-STAT 1 handheld.

- recharge the rechargeable battery installed in the i-STAT 1 handheld or a rechargeable battery installed in the recharging compartment of the DRC.
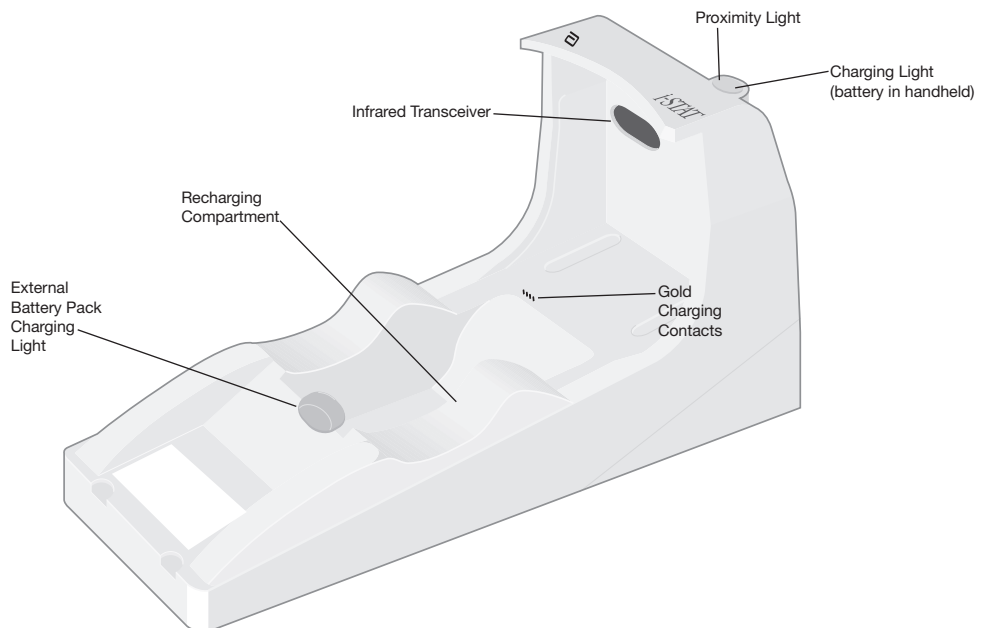
If you have questions regarding the information in this Technical Bulletin, please contact Abbott Point of Care Technical Support at 800-366-8020, option 1, or by email at techsvc@apoc.abbott.com.

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IDENTIFICATION OF THE NEW i-STAT 1 DOWNLOADER/RECHARGER

Previously, there were two separate versions of the i-STAT 1 Downloader/Recharger; one with serial connection capabilities to the Data Manager (DRS) and one with network connection capabilities to the Data Manager (DRN). To distinguish the new DRC from the previous DRS and DRN downloader/recharger versions, look at the Model Number label on the underside of the downloader/recharger. The new downloader/recharger will have a MN DRC-300 (Figure 1).

Figure 1

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SPECIFICATIONS OF THE DRC-300

Specification	
Size	4.12in (10.4cm) Wide 9.60in (24.4cm) Long 5.00in (12.7cm) High
Weight	1.2 lbs (0.55kg)
Power	AC-DC power adapter Input 12Vdc
Operating Temperature	0 - 40ºC 32 -104ºF
Storage Temperature	-20 - 50ºC -4 - 122ºF
Pollution Degree (Allowable ambient pollution level)	2
Installation Category (Allowable overvoltage specification)	2
Communication to Data Manager	USB, or Network
Communication Link to and From Handheld	Infrared Transceiver
Indicator LEDs Power Proximity Charge	N/A Blue Red/Green
Configuration	By host computer

Note: This product has been tested to the requirements of CAN/CSA-C22.2 No. 61010-1, second edition, including Amendment 1, or a later version of the same standard incorporating the same level of testing requirements.

POWER SUPPLY SPECIFICATIONS

Specification	
Input	100 – 240V- 50 – 60Hz 1.1A
Output	12Vdc 3A max

DRC INDICATOR LEDs

Handheld Battery LED (near top of the DRC)	
Off	No Rechargeable Battery
Blinking Red	Fast Charge Pending
Solid Red	Fast Charging
Solid Green	Trickle Charging

Spare Battery (near middle of DRC)	
Off	No Rechargeable Battery
Green	Trickle Charging

POWER REQUIREMENTS

The DRC requires one power outlet. The DRC must be used with the AC power supply adapter supplied with the DRC. Using the Y-Splitter cable, the DRC power supply can be used to supply power to the i-STAT Printer (Model Number PR-300), which reduces the number of power outlets required in the downloading and printing area.

CAUTIONS

- The DRC is not intended for use in the patient environment (within 1.5 meters of the physical location of the patient).

- Users should not connect the DRC to a medical electrical system.

- Do not place metal objects on or near the exposed gold charging contacts.

- Be sure to install all cables and power supplies so they do not post a trip hazard. Mount equipment so cables and accessories stay clear of walkways. The AC power supply adapter plug acts as a disconnect device for the DRC, and therefore, the socket outlet must be installed (or located) near the DRC and must be easily accessible.

- Use only the AC power supply provided with the DRC-300 to power the DRC-300.

- Only APOC provided printers may be connected to the DRC printer port.

- If using a Martel Printer, use the power supply that came with the Martel Printer and **not** the Y-Splitter cable provided with the DRC.

- A network cable and USB cable may NOT be connected to the DRC at the same time.

- If using rechargeable batteries to power the handheld, use only rechargeable batteries and recharging equipment supplied by your APOC distributor. Other batteries and rechargers may affect test results and pose other hazards to operators and patients.

- A falling handheld may cause injury. Always place the handheld and peripherals on a stable surface or in a location where it will not cause injury if dropped.

RUNNING CARTRIDGES IN A HANDHELD DOCKED IN THE DRC

All i-STAT Cartridges may be run in handhelds that are docked in the DRC.

DRC AFFECT ON AMBIENT OPERATING TEMPERATURE RANGE

The operating temperature for an i-STAT 1 handheld is 16ºC to 30ºC. The DRC and Rechargeable Battery may raise the temperature of the i-STAT 1 handheld 2ºC-3ºC relative to the ambient temperature if:

- The handheld is frequently lifted and replaced into the DRC

- Multiple cartridges are run in the handheld while it is in the DRC.

TRANSMITTING DATA FROM THE DRC TO THE DATA MANAGER

1. Place handheld in the DRC's cradle. If properly aligned, the blue proximity light will turn on and a "Waiting to Send" message will be displayed on the handheld until communication is established with the Data Manager.

2. Once the handheld establishes communication with the Data Manager, a "Communication in Progress" message will then appear on the handheld display and the arrows will circle until the transmission is complete.
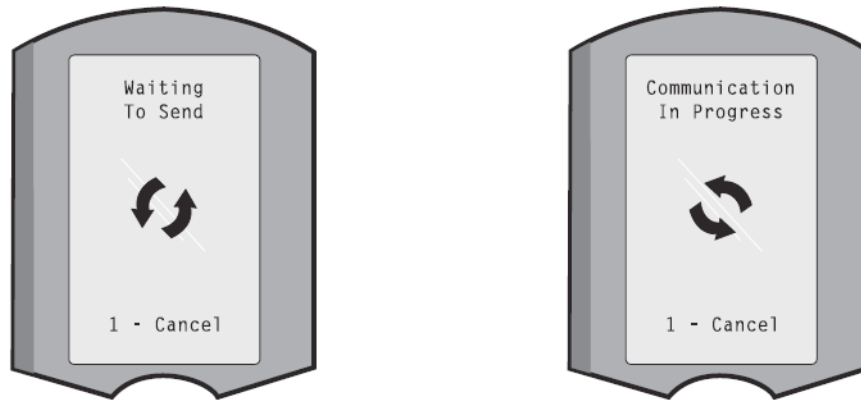
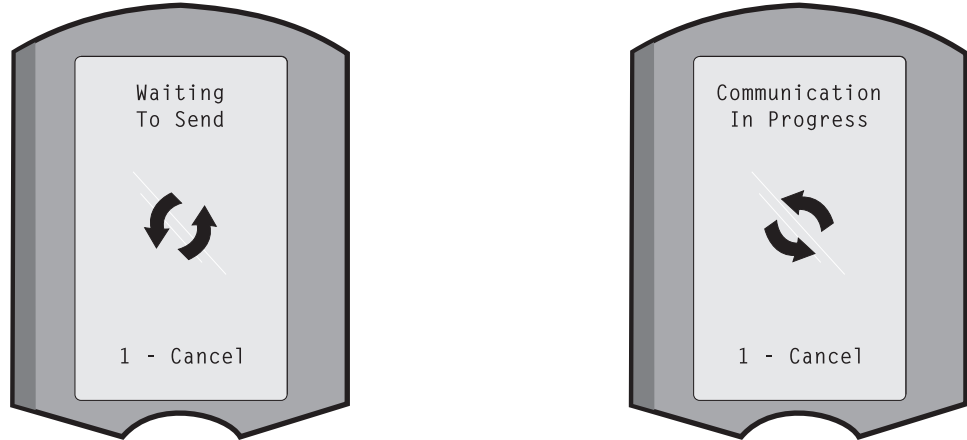**Note:** Do not move handheld until the "Communication in Progress" message disappears.

TRANSMITTED INFORMATION

The following information is transmitted from the i-STAT 1 handheld with each test record:

- Date and time the test was performed
- Operator and Patient ID or Quality Test fluid lot number
- All information entered by the operator, e.g. lot numbers, sample types, and comment codes
- Result(s)
- Serial number of the handheld
- Uses count on the handheld
- Application software version in the handheld
- CLEW standardization software in the handheld

CHARGING BATTERIES BEFORE USE

Place a new rechargeable battery in the recharging compartment on the DRC for 40 hours. The battery will then be 100% charged and ready for use. A handheld with disposable batteries may be placed on the DRC to download data until the rechargeable battery is ready.

RECHARGEABLE BATTERY LIFE

A fully charged battery, if not periodically recharged, will self-discharge in approximately 3 months. Prevent self-discharge of the battery by either:

- Keeping the rechargeable battery in a handheld that is periodically placed on the DRC, or
- Storing the rechargeable battery separately in the external charging bay on the DRC.

CHARGING A RECHARGEABLE BATTERY WHILE INSTALLED IN THE HANDHELD

Placing a handheld containing the rechargeable battery in the DRC will automatically initiate charging of the rechargeable battery. The indicator light on top of the DRC will be:

- green (trickle charge),
- red (fast charge), or
- blinking red (fast charge pending).

Note: No damage will be caused if a handheld with disposable batteries installed is placed in the DRC.

CHARGING A RECHARGEABLE BATTERY IN THE EXTERNAL RECHARGE COMPARTMENT

Placing a rechargeable battery into the external recharging compartment will automatically initiate trickle recharging. The indicator light near the recharging compartment will be green when a rechargeable battery is placed in the compartment.

1. The battery pack has 2 labels: one for orientation in the handheld and one for orientation in the DRC. With the label with the Downloader facing up and the electrical contact end of the pack facing the contacts in the battery compartment, insert the pack into the compartment as shown on the label.

2. To remove the battery after it is charged, back the pack out of the compartment.

CONFIGURING THE i-STAT 1 DRC FOR NETWORK OPERATION

This section includes procedures to configure the i-STAT 1 DRC to transmit data between the i-STAT 1 handheld and the Data Manager PC running the i-STAT Central Data Station (CDS) or i-STAT/DE. Successful programming of the i-STAT 1 DRC for network operation requires the completion of all of the following steps in chronological order.

Note 1: Example screenshots were captured with Windows® XP and are for example purposes only. The appearance of your screens may differ.

Note 2: To perform the following steps, it may be necessary to log into the Windows PC with Administrator rights.

Note 3: If the MAC address of the DRC is required, it will be displayed on the Current Settings screen, shown below at Step 10.

Note 4: It may be necessary to increase the number of simultaneous connections allowed by your data manager to 256 in order to maintain data transmissions to your data manager after installing a DRC-300 on your facility's network. This action does not apply when using a DRC-300 for USB serial communication.

The following instructions will increase the number of simultaneous connections allowed by your data manager (Central Data Station or i-STAT/DE):

Central Data Station (CDS) Customers

1. Shut down the Central Data Station program.
2. From your computer desktop, select **Start** and then **Run**.
3. In the **Open** field, type **WCDS32 configfull** then press **OK**.
4. At the i-STAT Central Data Station Customization window, select the **Network** tab.

Note: If the "Enable network communications" box is not checked then network communication is not enabled at your facility and these actions do not apply to you.

5. At the "**Maximum number of simultaneous network connections**" selection box, increase the number of connections to **<256>**
6. Click **Accept**. The Central Data Station will then automatically launch with 256 available connections.
7. You may now continue uploading as normal.

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Data Exchange (DE) Customers

i-STAT DE is used with Abbott Diabetes Care PrecisionWeb® and Medical Automation Systems RALSPlus®. Before starting with these steps, consult with your IT department. Steps 1 and 6 may require their support.

1. Identify the DE Server name. Use this information in step 2.
2. Using Internet Explorer, type http://< ServerName>/istatdesystem where **<ServerName>** is the DE Server name identified in step 1, into the address line and then press **ENTER**
3. At the i-STAT/DE System–Main/Status page, select **View/Set Configuration.**
4. At the "**Maximum simultaneous connections**" selection box, increase the number of connections to **<256>**.
5. Click **OK**.
6. Reboot the i-STAT DE Server. i-STAT DE will then start with 256 connections.
7. You may now continue uploading as normal.

1. **Preparation:** Determine for each DRC to be configured:

    - IP Address (on the same network as the Data Manager PC)
    - Gateway Address
    - Subnet Mask.
    - IP Address of Data Manager

2. **Windows 7: Do NOT connect the i-STAT 1 DRC to a PC.** Depending on the Domain policies, Windows 7 needs network connectivity in order to access network TCP/IP settings.

    Windows XP: Connect the i-STAT 1 DRC to a PC using a standard network cable as shown in the figure below. **Do not apply power to the DRC at this time.** If your PC is already connected to the network, unplug the network cable from the wall and connect it to the DRC.

    Note 2.1: Use a standard network cable. A crossover cable is not required.

① Power In
② Network Cable

POWER CORD
POWER SUPPLY
②
①
DOWNLOADER / RECHARGER
ETHERNET PATCH LEAD
CONFIGURATION PC
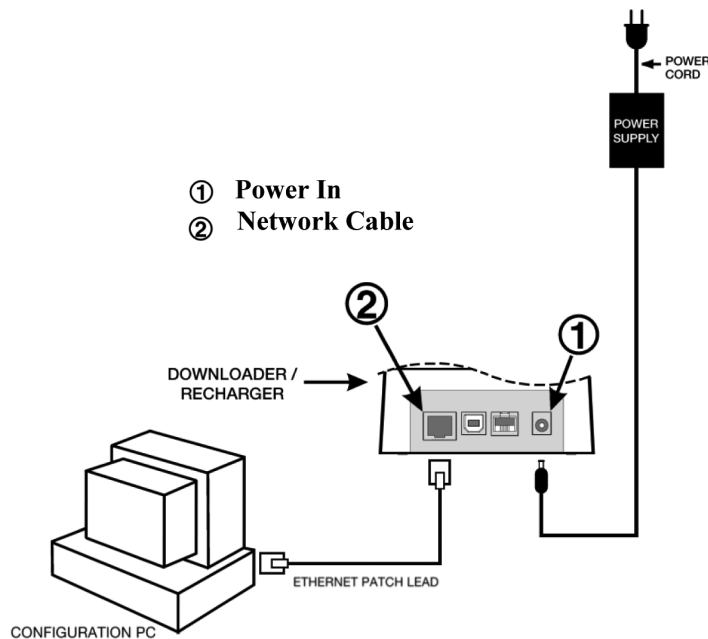
3. **Windows 7: Change the PC Network Configuration to detect the DRC.** On the PC, click **Start → Control Panel è Network and Internet (if shown, skip if not) → Network and Sharing Center → View network status and tasks.**

    Windows XP: Change the PC Network Configuration to detect the DRC. On the PC, click **Start → Settings → Control Panel → Network and Internet Connections (if listed) → Network Connections.**

4. Right click on "**Local Area Connection**" and select **Properties**.

5. **Windows 7:** In local area connection properties, verify that only ONE Internet Protocol version is checked. If multiple versions are checked, uncheck all until there is only ONE checked. Select that TCP/IP, then click **Properties**.
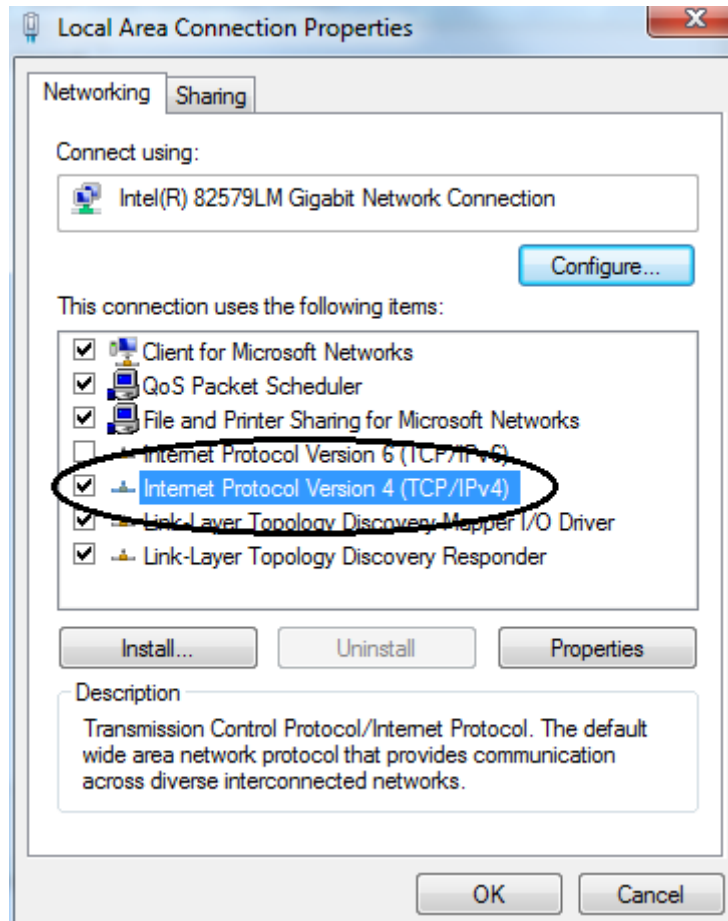
Windows XP: Select the **"Internet Protocol (TCP/IP)"** connection and click the **Properties** button.
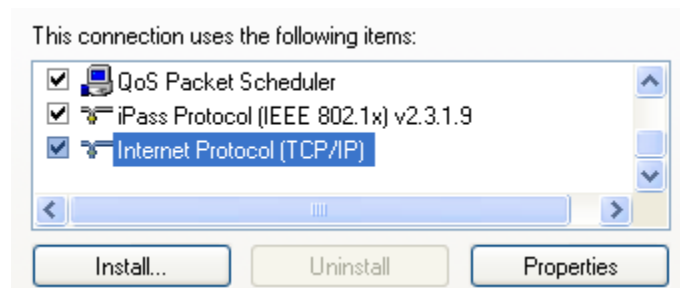
6. In the General tab, record all Internet Protocol (TCP/IP) Properties for later use.

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7. Select the **"Use the following IP Address"** radio button and input the following information:

- IP Address: 192.168.1.8
- Subnet Mask: 255.255.255.0
- Default Gateway: 192.168.1.1
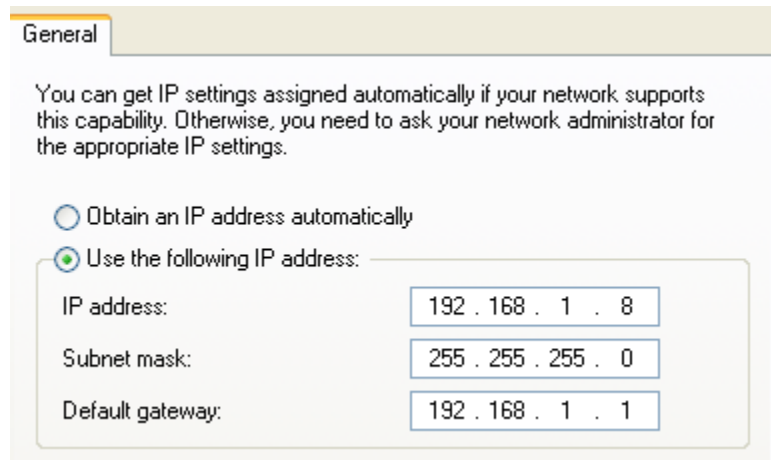
8. **Windows 7:** Unplug network cable from the wall and plug it into the back of the DRC-300 and apply power.

    Windows XP: Click **OK** and close all Control Panel windows. **Apply power to the DRC.**

9. Using Internet Explorer or another browser, navigate to http://192.168.1.10. The Abbott Point of Care Inc. i-STAT login screen should appear.

    Note 9.1: Internet connectivity is not required. Do not plug the computer into the facility's network.
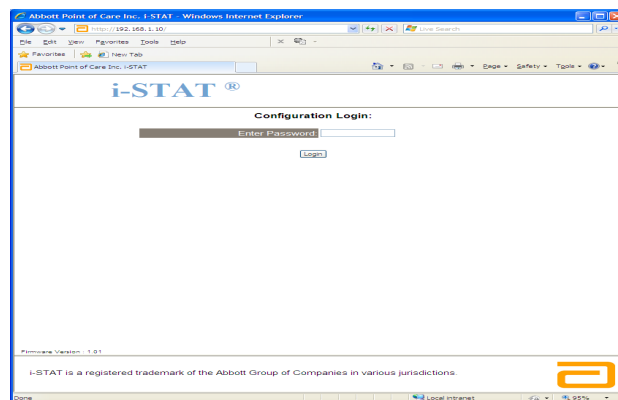
Note 9.2: If the webpage doesn't appear, check the following:

- Check to make sure the network cable is connected
- Check to make sure that power has been applied to the DRC.
- Check the proxy settings to make certain they are disabled.

    1. In Internet Explorer (version 6, 7 and 8) navigate to **Tools → Internet Options → Connections** tab **→ LAN Settings**.

    2. Under **Proxy server**, deselect the **Use a proxy server for your LAN** check box, if selected.

- Reset the DRC

If the webpage does not appear, the password to the DRC has been forgotten, or the DRC IP address settings are unknown, it is possible to *temporarily** reset all DRC settings back to factory default.

    1. Connect the network cable between the PC and the DRC, if not already connected. Press and hold the factory reset button (shown below) on the underside of the DRC while applying power, until the green light below the network connector on the back of the DRC illuminates.
    2. Once the DRC has been reset, go to Step 9 of this section

* The DRC will stay at the factory default settings until power to the DRC is disconnected, or until configuration is complete.

10. At the Configuration Login screen, enter your password and click **Login.** If a separate password has not been assigned, the default password is **"i-STAT"** and is case sensitive. Note: Abbott Point of Care Inc. recommends changing the default password. Following a successful login, the home page will appear.

    Note 10.1: The session will terminate after 15 minutes of inactivity, after which the user must re-enter their password.
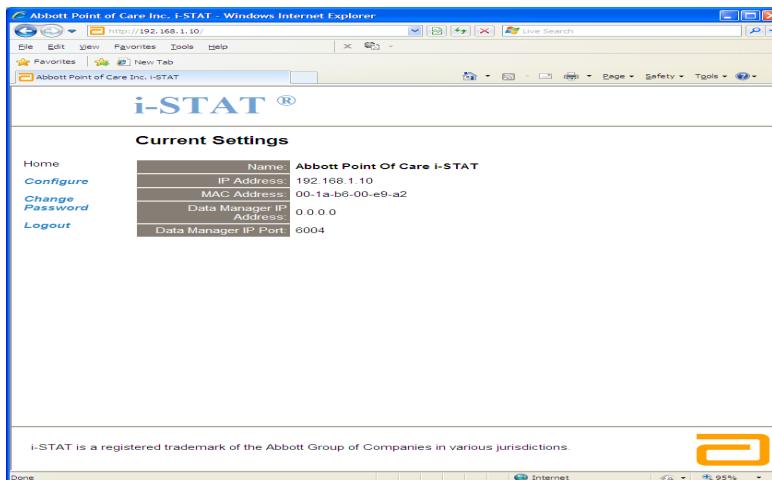
    Note 10.2: Should you wish to change the configuration password, perform the following steps:

- Under "Current Settings", click **Change Password.**
- Enter the existing password and the new password twice identically. Passwords must be 6-14 characters long and contain only the letters a-z, A-Z, digits 0-9 and the characters '-' (hyphen) and '_' (underscore).
- Click **Change Password.**

    Note 10.3: If the new password is forgotten later, it can be temporarily reset to the factory default (i-STAT) by resetting the DRC as described in Note 9.2. **However, please note that this will also reset the Downloader's Internal settings.**

11. Under "Current Settings", click **Configure.** The Configure Communication Settings page will appear.

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12. Determine the following site-specific information for this DRC:

- IP Address of the DRC
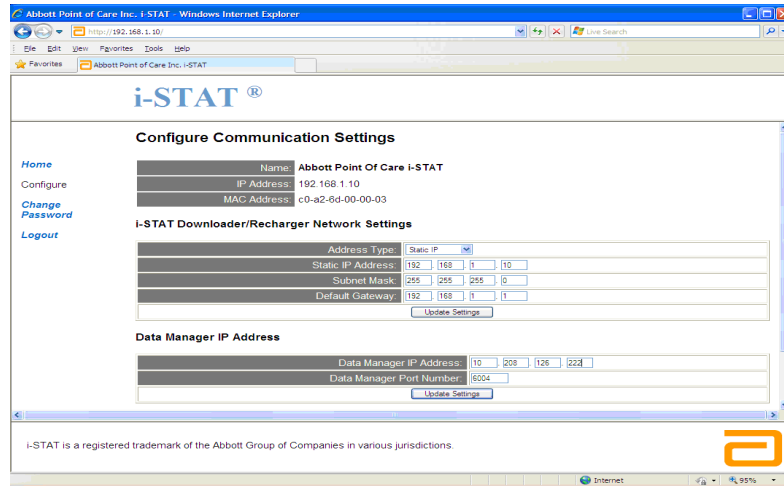
- Subnet Mask
- Default Gateway Address
- IP Address of the Data Manager
- Data Manager Port Number (Default is 6004)

Note 12.1: You must configure the "Data Manager IP Address" first, followed by the "i-STAT Downloader/Recharger Network Settings."

13. Scroll down to the "Data Manager IP Address" section, enter the Data Manager IP Address for this DRC and the Data Manager Port Number (default is 6004), and click **Update Settings.**
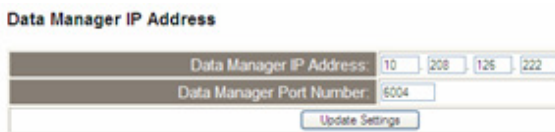
14. Once back to the "Current Settings" screen, click **Configure.**

15. Scroll to the "i-STAT Downloader/Recharger Network Settings" section, and select the address type for assigning the IP Address of the DRC being configured:
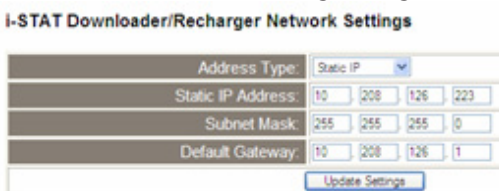
16. To configure for a static IP address, follow the instructions in 16A. To configure for DCHP, follow 16B.

Note 16.1: Static IP addresses are required when using handheld customization by Download Locations.

16A. If you want to configure the DRC with a static IP Address, select **"Static IP"** from the Address Type drop down menu, and enter the assigned IP Address, Subnet Mask, and Default Gateway for the DRC and click **Update Settings.**
16B. If you want to use the DHCP server, select **"DHCP"** from the Address Type drop down menu and click **Update Settings.**

After completion, the following screen will be displayed.
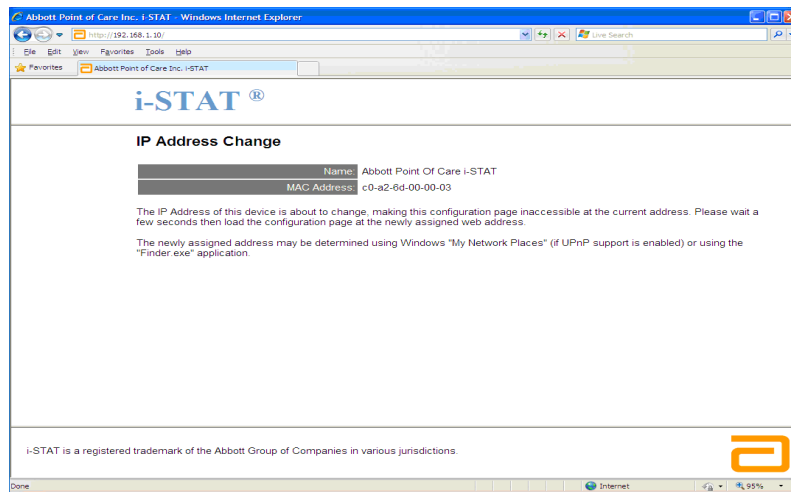
17. If additional DRCs require configuration, connect the next DRC to the PC per step 2 and apply power to the DRC and repeat steps 9 through 16. Otherwise, proceed to step 18.

RESTORING THE PC'S NETWORK CONFIGURATION:

18. **Windows 7: Disconnect the Ethernet cable from the DRC and connect to the network.** On the PC, click **Start → Control Panel → Network and Internet (if shown, skip if not) → Network and Sharing Center → View network status and tasks.**

   Windows XP: Disconnect the Ethernet cable from the DRC and the PC. On the PC, click **Start → Settings → Control Panel → Network and Internet Connections (if listed) → Network Connections.**

19. Right click on "**Local Area Connection**" and select **Properties**.

20. Select the "**Internet Protocol (TCP/IP)"** connection and click the **Properties** button.
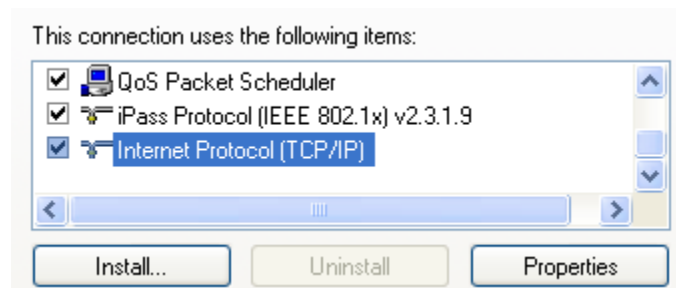
21. Restore Internet Protocol (TCP/IP) properties in the General tab to the network settings recorded in Step 6.

22. **Windows 7:** Check the additional internet protocol(s) previously unchecked in Step 5.

   Windows XP: Click **OK** and close all Control Panel windows.

23. **Windows 7:** Proceed to Step 24.

   Windows XP: Connect the network cable from the PC to the network (wall).

24. To connect the configured DRC for transmission to the Data Manager, follow the instructions in the **Wiring the Downloader/Recharger** sections below.

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CONNECTING AND WIRING THE DRC FOR NETWORK COMMUNICATION

The following diagram shows how to connect the portable printer to the DRC and the DRC to the network for communication to the Data Manager. The required parts are:

- Printer Interface Cable
- Downloader Recharger Power Supply
- Y-Splitter Cable (Optional)
- Network Cable
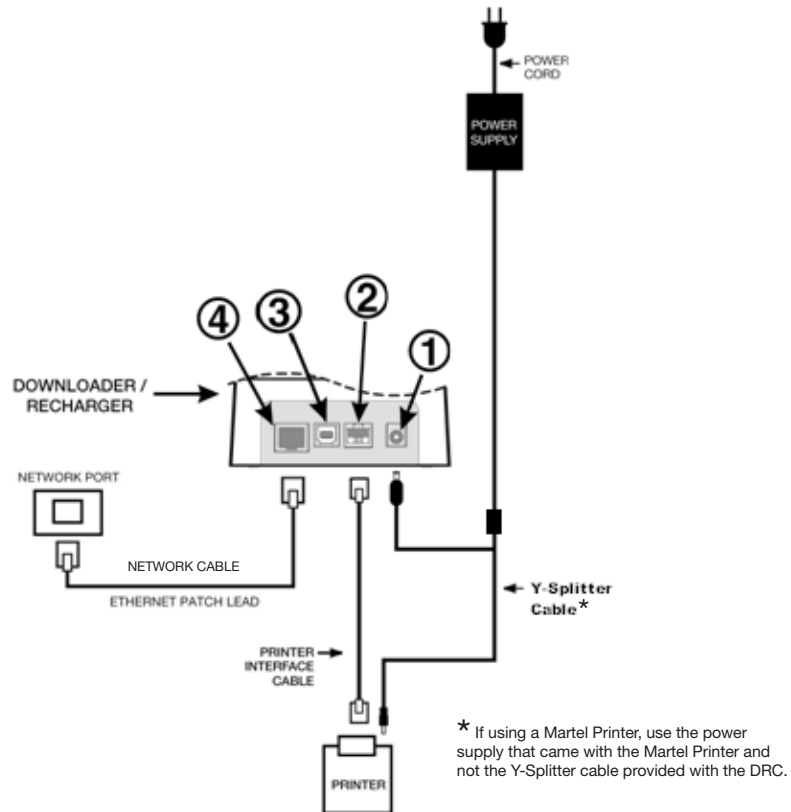
Note: Once the DRC has been configured and connected to the facility's network, you can view the DRC's configuration page by using Internet Explorer and navigating to the DRC's configured IP Address using any computer on the same node of the network.

CONFIGURING THE i-STAT 1 DRC FOR SERIAL OPERATION

To install the USB drivers for the DRC, it is necessary to be logged into a Windows PC with Administrator rights.

Note: If internet access is not available, obtain the i-STAT 1 D/R USB Driver CD-ROM (Abbott L/N 04P75-05) from Abbott Customer Service. After receipt of the CD-ROM, proceed to Option 2, Step 3.

Option 1: Installation Using Windows Hardware Wizard (Internet Required)

This method requires a PC connected to the Internet and to have user permission to receive and install Windows Updates.

1. Apply power to the DRC. Connect the USB cable from the DRC to the PC. A "Found New Hardware Wizard" box will appear.

2. Allow Windows to connect to Windows Update to search for software by selecting the **"Yes, this time only"** radio button and clicking **Next.**

3. Select the **"Install the software automatically (Recommended)"** radio button and click **Next.**
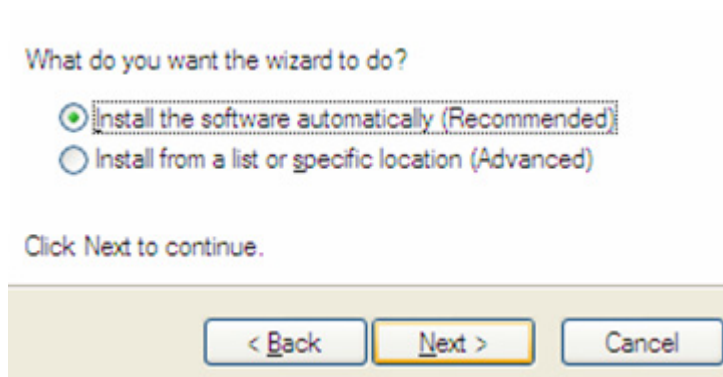
4. Wait while the "USB Serial Converter" driver (FT23R USB UART) installs. This may take a few minutes.

5. When the "USB Server Converter" driver installation is complete, click **Finish.**

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6. Another "Found New Hardware Wizard" will appear automatically. Select the **"Yes, this time only"** radio button and click **Next** to continue.

7. Select the **"Install a software automatically (Recommended)"** radio button as previously illustrated and click **Next.**

8. Wait while the "USB Serial Port" driver installs. This may take a few minutes.

9. When the "USB Serial Port" driver installation is complete, click **Finish.** If the DRC USB driver installs successfully, you will see a "Found New Hardware" message appear on the PC Taskbar.
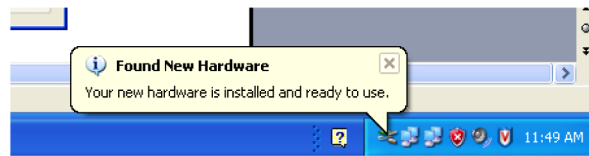
10. Select **Start → Settings → Control Panel → Performance and Maintenance (if listed) → System** to launch the "System Properties" dialog box. Select the **Hardware** tab, and click **"Device Manager"** to show a list of devices.
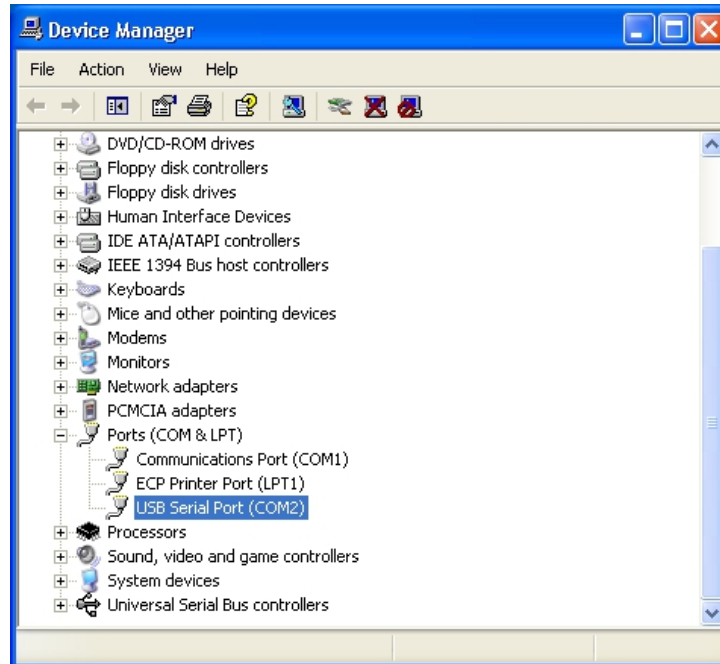
11. Expand "Ports (COM & LPT)" to list all the COM Ports (as shown above). The newly installed DRC port is named "USB Serial Port".

12. Right click on the **"USB Serial Port"** device entry and select **Properties.** A "USB Serial Port Properties" dialog box will open. Select the **Port Settings** tab.
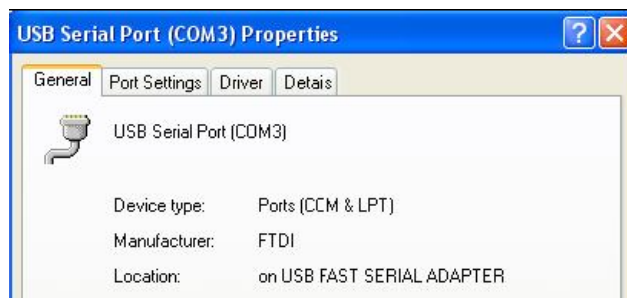
13. Using the drop down menu, set the **"Bits per second"** to 38400. Other drop down menus should remain as the default.
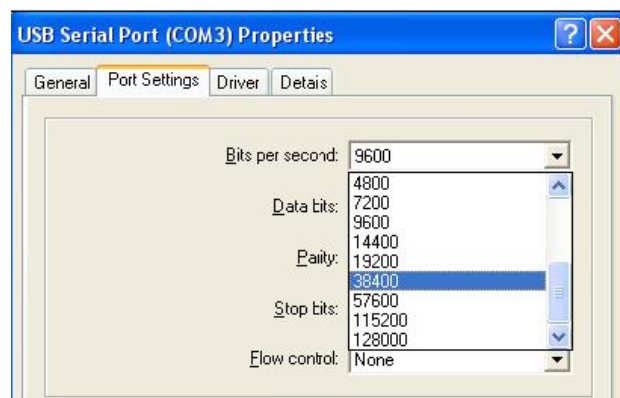
14. Click **Advance Settings.** Using the drop down menu, change the port number to the lowest available number. Determine availability by viewing the existing comports in Device Manager. Click **OK** twice.

15. Close all **Control Panel** windows.

Option 2: Installation Using a Driver Installer File

Note: If a CD-ROM with the USB driver has been obtained, proceed to Step 3 below. If not, continue with Step 1.

1. Using Internet Explorer or another browser, navigate to http://www.abbottpointofcare.com/ Customer-Support.aspx.

2. The following link is listed under the "Useful Customer Information" section:

  • USB Driver for DRC-300 Downloader/Recharger
      ○ This link allows you to download a utility file (CDM20802_Setup.exe) which can be used to install FTDI USB drivers on a PC that you wish to use for USB connections with the DRC-300.

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3. **Run the "CDM20802_Setup.exe"** USB Serial Converter Device Driver Setup file. **For safe installation, disconnect any USB-Serial converter devices from the PC before running CDM20802_Setup.exe.** Follow the on-screen instructions to complete the installation (If present).

4. Connect the DRC to the PC using the USB cable, as per the "Connecting and Wiring the i-STAT 1 DRC for Serial Communication" section below.

5. Apply power to the DRC. The following notifications as shown below should be displayed.

6. Select **Start → Settings → Control Panel → Performance and Maintenance (if listed) → System** to launch the "System Properties" dialog box. Select the **Hardware** tab, and click **"Device Manager"** to show a list of devices.
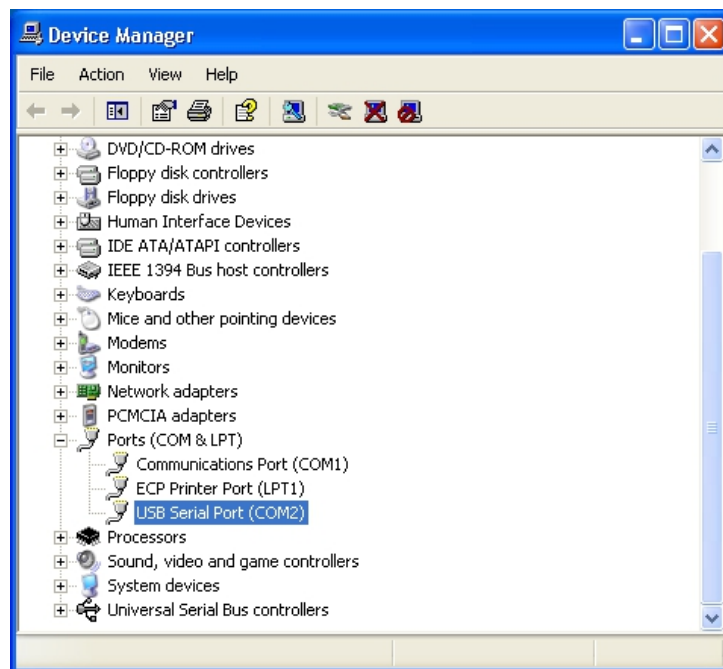
7. Expand "Ports (COM & LPT)" to list all the COM Ports (as shown above). The newly installed DRC port is named "USB Serial Port".

8. Right click on the **"USB Serial Port"** device entry and select **Properties.** A "USB Serial Port Properties" dialog box will open. Select the **Port Settings** tab.
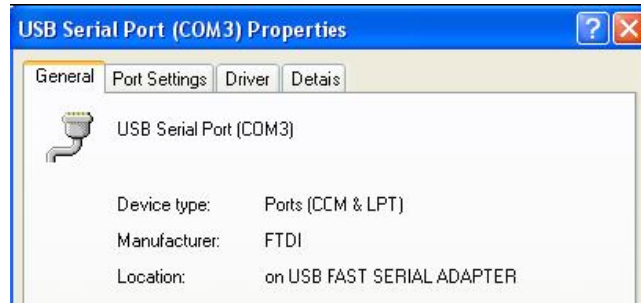
9. Using the drop down menu, set the **"Bits per second"** to 38400. Other drop down menus should remain as the default.
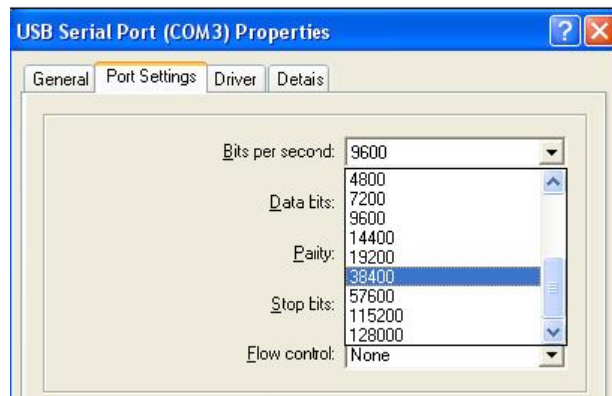
10. Click **Advance Settings.** Using the drop down menu, change the port number to the lowest available number. Determine availability by viewing the existing comports in Device Manager. Click **OK** twice.

11. Close all **Control Panel** windows.

CONNECTING AND WIRING THE i-STAT 1 DRC FOR SERIAL COMMUNICATION

Note: For successful data transmission to occur, the USB cable should first be connected between the DRC and the PC prior to installing or opening the CDS or Jammlite applications.

The following diagram shows how to connect the DRC to the Data Manager via USB connection, and how to connect the portable printer to the DRC for communication. The required parts are:

- USB Cable
- Printer Interface Cable
- Downloader Recharger Power Supply
- Y-Splitter Cable (Optional)

① Power In
② RJ12 (printer interface)
③ USB

*If using a Martel Printer, use the power supply that came with the Martel Printer and not the Y-Splitter cable provided with the DRC.
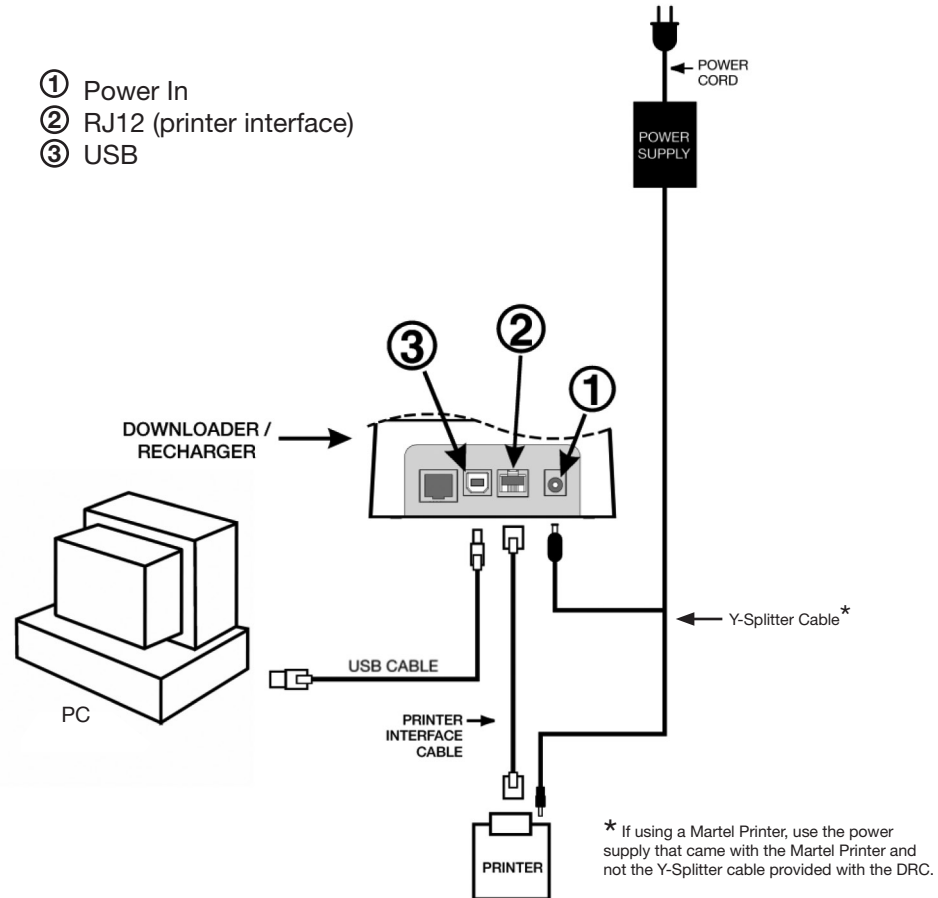
USB DRIVER UNINSTALLATION

1. USB Driver Uninstallation for Windows XP

Caution: Disconnect the DRC-300 from the PC before proceeding.

1.1 Using Internet Explorer, navigate to:
        http://www.abbottpointofcare.com/Customer-Support.aspx

1.2 The following link is listed under the "Useful Customer Information " section:

- USB Driver **Uninstaller** for DRC-300 Downloader/Recharger.
    - This link allows you to download a utility file (**CDMuninstallerGUI.exe**) which can be used to uninstall FTDI USB drivers from a PC.

Note 1.1: This utility is only compatible with Windows XP and higher.

Note 1.2: Other FTDI USB device drivers with vendor ID: 0403 and ProductID: 6001 will be uninstalled using the same uninstallation process.

- Instructions for the Windows XP USB Uninstaller utility can be found on the FTDI website at www.ftdichip.com

2. USB Driver Uninstaller for Windows 2000

2.1 Connect the DRC-300 USB cable to the PC.

2.2 Select **Start → Settings → Control Panel → Performance and Maintenance (if listed) → System** to launch the "System Properties" dialog box.

2.3 Select the **Hardware** tab, and click **Device Manager** to show the list of devices.

2.4 Expand "Ports (COM & LPT) to list all the COM Ports. Right-click on the **USB Serial Port** device entry associated with the DRC and select **Properties**. A "USB Serial Port Properties" dialog box will open.

2.5 Select the **Driver** tab. Click **Uninstall** and then click **OK** when the warning message appears.

CONFIGURING THE CDS SOFTWARE FOR SERIAL COMMUNICATION

See the Central Data Station section of the i-STAT 1 System Manual for instructions on configuring the CDS application for receiving serial data transmissions.

i-STAT is a registered trademark of the Abbott Group of Companies in various jurisdictions.

MARTEL Printer

Overview	The printer can receive data directly from the analyzer via IR transmission or through a data cable connected to a Downloader. The printer can be recharged from a power adapter connected to an outlet.

Specifications

Dimensions	Height: 64mm Width: 135mm Depth: 130mm
Weight	425g (Approx.)
Power	1. 4.8V Nickle Metal Hydride battery pack. 2. Power adapter for AC outlet 3. Downloader
Communication Link	1. Infra-red 2. RJ12
Paper	5.7cm thermal
Switch	On/Off
LED Indicator Lights	POWER: Green STATUS: Amber
Printing method	Thermal line printing
Printing speed	10 lines per second
Temperature	Operating: 0 °C to 50 °C (32-122°F) Storage: -20 °C to 60 °C (-4-140°F) Charging: 10 °C to 45 °C (50-113°F)

Paper Cup

Top view of Martel Printer

Paper Outlet

Side view of Martel
Printer

Power Connector

On/Off Switch

IR LED
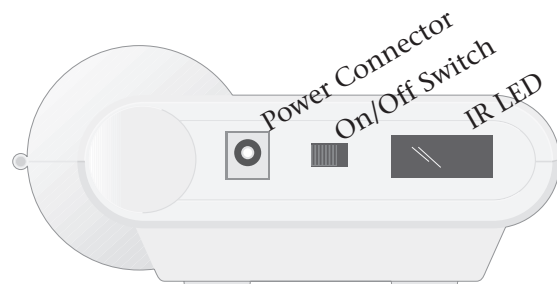
RJ12 Connector
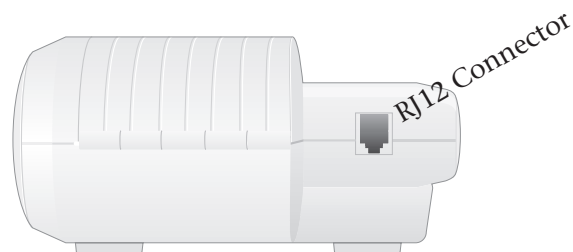
Back view of Martel
Printer

Supplies Provided with Printer

✧ Adapter and power cord

✧ One roll of paper

Power

The printer is turned on using the switch on its left side. When the printer is on, the Power LED will be green. The plug for the AC adaptor is also on the left side.

For printer serial numbers below 240223657, the rechargeable battery is trickle charged when the printer is turned on or off and connected to an AC outlet. Before putting these serial number printers into use, the printer should be turned off and the battery charged for 16 hours.

For printer serial numbers above 240223657, the power LED may flicker when connected to the power supply and the switch is in the OFF position. This flicker indicates that the printer is fast charging. Fast charging occurs only when the printer is turned off. Trickle charging occurs when these printers are plugged in and turned on, but not in use. Printers above serial number 240223657 indicating low battery will charge to full capacity in 9 hours, if charged from a 12V supply with the power switch off.

The battery needs to be recharged for all printer serial numbers when the Status LED lights continuously during printing. If the battery becomes exhausted, printing will become faint, erratic, or not possible at all. Should this happen, turn the printer off and allow to recharge for 1 hour before attempting printing again

Paper

Paper may be ordered along with other supplies for the i-STAT System or paper with the following specifications can be used:

✧ Black print thermal paper

✧ 2.25" (5.7 cm) wide by 80' (25 m) long

✧ Paper grade: TF50KS-E2C

The Status light will flash to indicate that the paper has run out.

To replace the paper, open the paper cup lid by squeezing the lid as shown in the illustration and remove any remaining paper by pressing the Paper Feed button. **Do not pull paper through the printer mechanism.** Reel off a few centimeters from a new roll of paper and check that the end has clean straight edge. Slide the leading edge of the paper through the paper entry slot, with the leading edge of the paper feeding forwards from the bottom of the roll, until you feel resistance. Press the paper feed button and feed the paper through the printer mechanism. Keep the paper feed button depressed until enough paper is fed through the printer mechanism to pass through the paper exit slot. Sit the new paper roll in the paper cup and close the lid.

Should the paper become creased or out of line when feeding a new roll, cut the end off the paper roll, feed out the creased paper using the Paper Feed button, and reload ensuring the paper has a clear straight edge.

Before use, open the paper cup lid and ensure that the paper roll is present. Close the lid, ensuring that the paper passes through the paper exit slot. Turn the printer on. The Power indicator will light and the printer mechanism will reset.
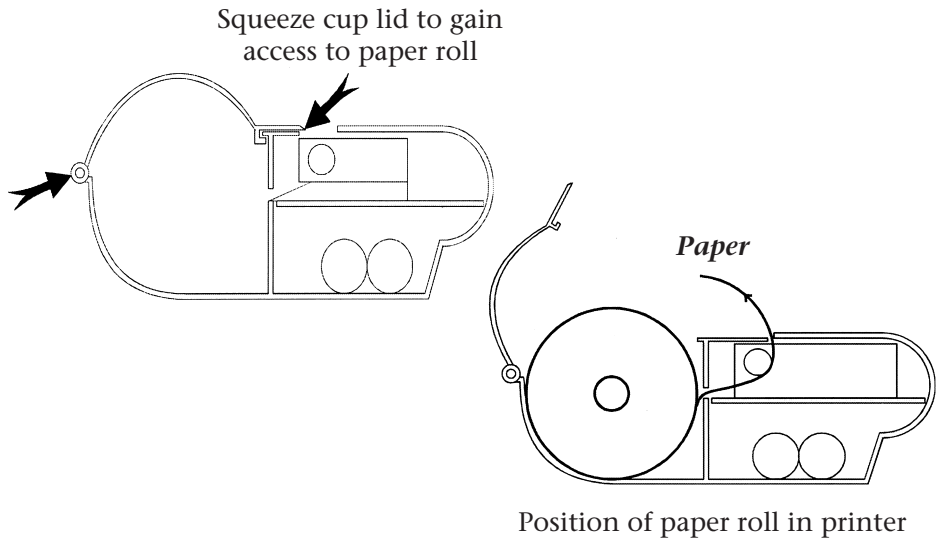
Squeeze cup lid to gain
access to paper roll

Paper

Position of paper roll in printer

When removing a printout from the printer, pull the printout toward the front
of the printer and tear from one side to the other across the serrated edge.

Serrated Edge

Paper

Using serrated edge
to tear paper
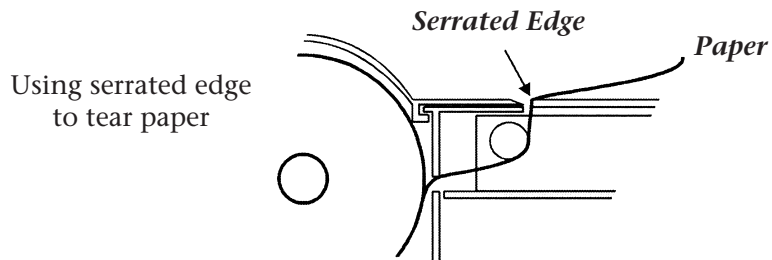
**Printing Directly
from the Analyzer**

Before printing ensure that the printer is turned on. The printer is turned on
and off using a switch on the left side of the printer. When the printer is on
the Power LED will be green.

To print directly from the analyzer, point the analyzer's Infrared Communication
Window at the printer's IR LED window on its left side, ensure that the results
to be printed are displayed, and press the Print key on the analyzer. The printer
must be within 1 to 5in. (2.5 to 12.7cm) of the analyzer and must not be too close
to the analyzer. Do not move the analyzer or printer until printing is complete.

**Printing Via a
Downloader**

See the Downloader Wiring and Programming section of this manual for
directions to connect the printer to a Downloader or Downloader/Recharger.
Before printing ensure that the printer is turned on. The printer is turned on
and off using a switch on the left side of the printer. When the printer is on
the Power LED will be green.

Place the analyzer between the arms of the Downloader or in the Downloader/
Recharger, ensure that the results to be printed are displayed, and press the Print
key. Do not move the analyzer or printer until printing is complete.

Printing Many Results

Select **2 – Data Review** from the Administration Menu on the analyzer, then select **7 – List**. Use the arrow keys to page up and down through the pages of stored results. Press the numbered key for each test record to be printed. To deselect a record, press that numbered key again. When all test records have been selected, align the printer and analyzer according to the directions under Printing Directly from an Analyzer or place the printer in a Downloader or Downloader/Recharger according to the directions above, and press the Print key.

What is Printed

```
---------------------
i-STAT EG7+

Pt : 11
Pt Name : _____
      .........................
37.0°C
pH          7.527
PCO2       34.3 mmHg
PO2          35 mmHg
BEecf         6 mmol/L
HCO3         28 mmol/L
TCO2         30 mmol/L
sO2          75 %
      .........................
Na          131 mmol/L
K           4.3 mmol/L
iCa         1.17 mmol/L
Hct          52 %PCV
Hb*          18 g/dL
    *via HCT

Sample Type : VEN
CPB : No

13:32    15AUG00

Operator ID: 11
Physician: _____

Serial: 300098
Version: JAMS104A
CLEW: A64
```

Name of Test	i-STAT cartridge type
Sample ID	Patient ID or type of quality test and lot number of solution tested
Results	Results are printed with units as well as flags and comment codes if applicable.
At Patient Temperature	If the patient's temperature was entered on the Chart Page, a second set of results is displayed for blood gases at the patient's temperature.
Sample Type	Sample type selected from Chart Page when sample is patient or proficiency test
Free Fields	Information entered into the free fields on the Chart Page when sample is patient or proficiency test
Time and Date	Time and Date when test was performed
Operator ID	Operator ID
Lot Number	Lot number of cartridge
Serial	Serial number of the analyzer
Version	Analyzer application software
CLEW	Standardization software

Caution

⬦ Use only a rechargeable battery pack purchased from Abbott Point of Care. Rechargeable battery packs not recommended by or purchased from Abbott Point of Care may be susceptible to overheating and could lead to a potential fire or burn hazard.

⬦ Use power supply provided with printer.

⬦ Do not operate the printer without paper.

⬦ Do not allow the power supply to become a trip hazard.

⬦ Do not disturb the analyzer or printer until printing is complete since this will interrupt the printout. If printing is interrupted, realign the printer and analyzer or replace the analyzer in the Downloader to resume printing. Note: If significant time has elapsed, some results may be missing from the printout. Reprint the results.

⬦ If printed results appear inconsistent with a patient's clinical assessment, verify that the printed results match the data in the analyzer. If the results do match, the patient sample should be retested using another cartridge. If they do not match, reprint the results. If the reprint still does not match the analyzer data, the printer requires service and the printed results must not be used.

Troubleshooting   Printer not printing. Power LED on and Status LED off:

◇ check that results are displayed or that results have been selected from List under Data Review.

◇ check that that distance between analyzer and printer, if printing directly from the analyzer, is not too short or too long.

◇ perform printer self test to ensure that printer is functioning. Turn the printer on while pressing the Paper Feed button, then release the Paper Feed button and ensure that the printout is clear.

Paper is feeding but nothing is printed: check that the paper is feeding from under the roll.

Printer not printing and Status light on continuously: battery needs to be recharged.

Printer Power LED does not come on when printer turned on: battery needs to be recharged. The power adapter cannot supply sufficient for printing so the battery needs to be partially charged before printing is possible.

Printer not printing and Status light flashing at rate of 0.5 seconds: printer is out of paper.

Printer not printing and Status light flashing at rate of 0.25 seconds: print head temperature too hot. Printing will be suspended until print head temperature returns to normal level.

THE i-STAT PRINTER

OVERVIEW

This section describes the instructions for using the new i-STAT Printer, which is used to print results from all models of the i-STAT 1 Analyzer (handheld).

Note: This printer cannot be used with the i-STAT Portable Clinical Analyzer (PCA).

Paper Feed Button   Power Button   Paper Release Lever

Power Indicator

Status Indicator

IR Window

i-STAT

DATA   12VDC   Power Connection

Data Connection
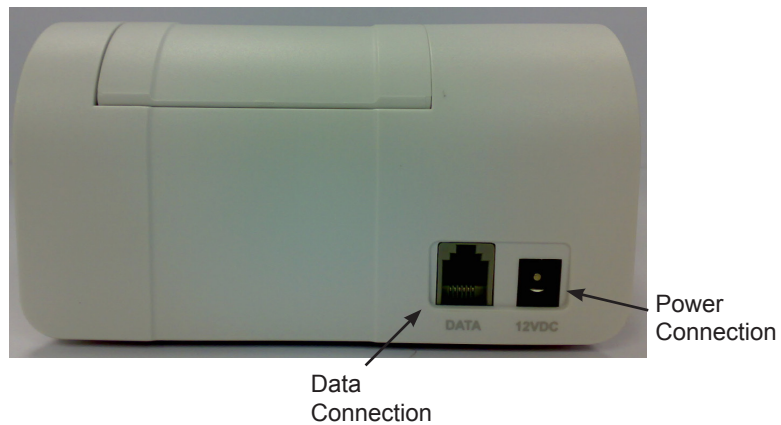
SPECIFICATIONS

Dimensions	Height: 72.5mm Width: 136mm Depth: 120mm
Weight	500g (Approx.)
Power	1. 4.8V NiMH rechargeable battery pack 2. Power adaptor for AC outlet
Communication Link	1. Infra-red 2. RJ12
Paper	5.7cm thermal
Buttons	1. On/Off 2. Paper Feed
LED Indicators	POWER: Green/Orange/Red STATUS: Green/Orange/Red
Printing Method	Thermal line printing
Printing Speed	Battery: Up to 10 lines per second AC Adaptor: Up to 2.5 lines per second
Temperature	Operating: 15ºC to 40ºC Storage: -20ºC to 50ºC
Printer Power Requirements	The printer is rated at: • 12Vdc • 1.5A max • 18W
External Power Supply Unit (PSU)	The external PSU is rated at: • 100-240Vac • 50-60Hz
Fuses	There are no operator replaceable fuses with the i-STAT Printer.

Note: This product has been tested to the requirements of CAN/CSA-C22.2 No. 61010-1, second edition, including Amendment 1, or a later version of the same standard incorporating the same level of testing requirements.

i-STAT PRINTER KIT COMPONENTS AND ACCESSORIES

The following individual components are included in the i-STAT Printer kit:

1. i-STAT Printer
2. AC adapter
3. Power Cord
4. Rechargeable Battery
5. One roll of printer paper (not shown below)

ORDERABLE COMPONENTS

The following individual i-STAT Printer kit items can be ordered separately from Abbott Customer Service for replacement or supplemental inventory purposes.

ORDERABLE ITEM	ABBOTT LIST NUMBER
i-STAT Printer	04P74-01
i-STAT Combo Power Supply	04P74-02
Rechargeable Battery for the i-STAT Printer	04P74-03
Portable Printer Paper (6 rolls per box)	06F17-11
i-STAT Printer Kit	04P74-04

i-STAT PRINTER PAPER

Printer paper may be ordered along with other supplies for the i-STAT System **(Abbott List # 06F17-11).**

The STATUS indicator will illuminate to indicate the print status:

Ready: **Green**   ●
Out of Paper: **Orange**   ●
Error: **Red**   ●

Paper for the i-STAT Printer can be installed or replaced as follows:

1. Open the paper compartment lid by pulling the release lever as shown in the printer illustration on page 1 and remove any remaining paper.

2. Reel off a few centimeters of paper from the new paper roll, with the leading edge of the paper feeding forward from the bottom of the roll.

3. Sit the new paper roll in the compartment such that the leading edge is resting outside the compartment on the printer casing.

4. Close the lid until it snaps into place.

Note 1: Should the paper become creased or misaligned, simply reload the paper as described above ensuring that the paper has a clean, straight edge.

Note 2: When removing a printout from the printer, pull the printout toward the front of the printer and tear from one side to the other across the serrated edge.

i-STAT PRINTER POWER

There are three options for powering the i-STAT Printer:

- Using the AC adapter and power cord only,
- Using the Rechargeable Battery only, and
- Using the Rechargeable Battery with the AC adapter and power cord.

The i-STAT Printer can be turned on and off by pressing the POWER button. When the printer is on, the POWER indicator will be illuminated:

Power OK: **Green**   ●
Battery Low: **Orange**   ●
Battery Empty: **Red**   ●

If the printer is inactive for >60 seconds, it will automatically enter the power-saving mode. When in the power-saving mode, the POWER indicator will change from a solid color light to pulsed illumination.

The printer's rechargeable battery needs to be recharged when the POWER indicator turns orange. If the battery becomes exhausted, the POWER indicator will turn red and printing will be disabled.

The printer's battery can be recharged using the supplied AC power adapter. The socket for the AC power adapter is located on the rear of the printer. Note: Charging only occurs when the printer is switched off or in the power-saving mode. A full charge takes approximately 3 hours.

Symptoms Indicating that the Rechargeable Battery Requires Replacement:

1. A steady Orange or Red POWER indicator light on the printer, even after charging it for the recommended 3 hours.

2. Loss of battery capacity, indicated by a shorter interval between charges.

Installing or Replacing the Rechargeable Battery in the i-STAT Printer:

1. Disconnect the printer from the AC adapter.

2. Turn the i-STAT Printer upside down and place it on a flat surface. Remove the battery door by sliding it off while pressing on the grooved section. Set the door aside.

3. If replacing an existing rechargeable battery in the printer, disconnect the existing battery by gently pulling up on the red/white/black wires until the connector releases from the three metal pins. Once the battery is disconnected, remove it completely from the battery compartment.

4. Remove the new rechargeable battery from its packaging. With the thumb and index finger of one hand, grasp the connector at the end of the red/white/black battery wires.

5. Assure proper connector alignment as shown.
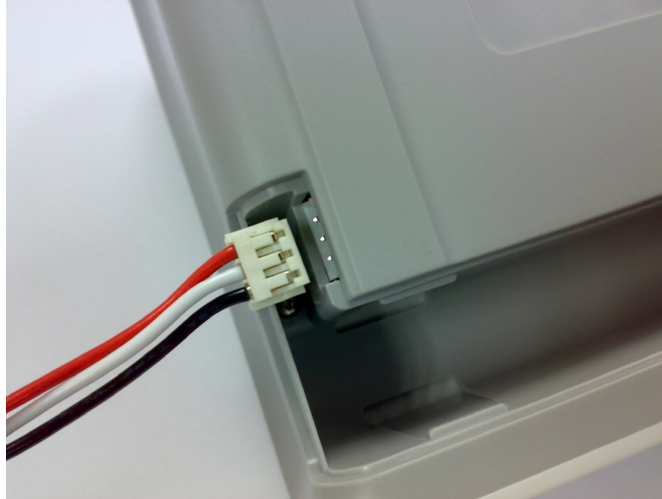
6. Slide the connector onto the three metal connector pins.
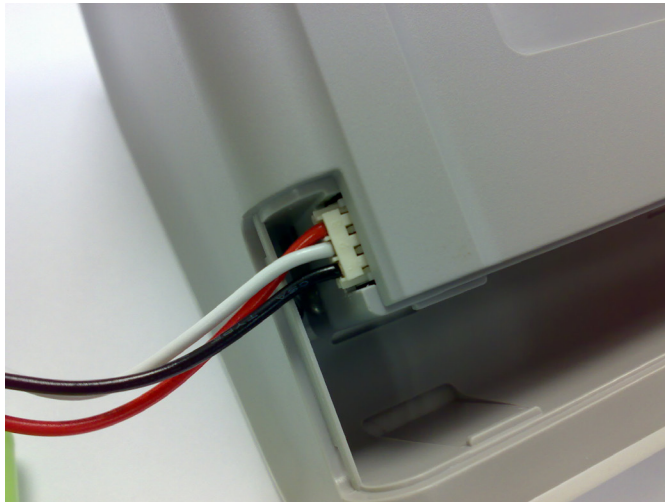
7. Once the wires are connected, place the battery portion of the pack into the rectangular compartment. Make sure the wires are not under the battery or projecting out of the opening. The correct positioning is shown below.

8. Slide the battery door back onto the compartment until it closes and locks into place.

9. Turn the printer over, plug it back into the AC power adapter, and charge the new battery in the printer for a minimum of 3 hours before use.

Note: If the rechargeable battery is removed or becomes exhausted, it is still possible to print at reduced speed using the AC power adapter.

Powering the i-STAT Printer Using the AC Adapter and Power Cord:

1. Connect the power cord to the AC adapter as shown.

2. Plug the round connector from the AC adapter into the 12VDC port on the back of the i-STAT Printer.

3. Plug the power cord into a wall outlet.

PRINTING DIRECTLY FROM THE i-STAT 1 HANDHELD

1. Ensure that the printer is turned on and that the POWER indicator is green.

2. Align the handheld's IR communication window with the printer's IR LED window. Generally, the printer must be within 1 to 5 inches (2.5 – 12.7 cm) of and not too close to the handheld.

3. Display the results to be printed on the handheld.

4. Press the 🔲PRT key on the handheld. Do not move handheld or printer until printing is complete.

5. If printer is not powered from a wall outlet using the AC adapter, turn printer off.

CONNECTING THE i-STAT PRINTER TO A DOWNLOADER OR DOWN-LOADER/RECHARGER

The Downloader Programming and Wiring section of the i-STAT 1 System Manual describes directions for connecting the i-STAT Printer to a Downloader or Downloader/Recharger.

Note: the following two options **ONLY** can be used to connect the i-STAT Printer to a Downloader or Downloader/Recharger:

Type of Downloader or Downloader/Recharger Being Connected to the i-STAT Printer	Location of Connection Diagram in Downloader Programming and Wiring Section
Network Downloader or Downloader/Recharger	Page 21-6 (Option 1)
Serial Downloader or Downloader/Recharger	Page 21-9 (Option 2)

PRINTING VIA A DOWNLOADER OR DOWNLOADER/RECHARGER

1. Place i-STAT 1 handheld in a Downloader or Downloader/Recharger that is connected to the i-STAT Printer.

2. Display the results to be printed on the handheld.

3. Press the ⬛PRT key on the handheld. Do not move handheld or printer until printing is complete.

4. If printer is not powered from a wall outlet using the AC adapter, turn printer off.

PRINTING MANY RESULTS

1. Turn the i-STAT 1 handheld on.

2. Press the Menu key to bring up the Administration Menu.

3. Press **2 – Data Review.**

4. Press **7 – List**.

5. Scroll through the results using the ← and → keys.

6. Press the number key for the test record(s) to be printed. (Press the numbered key again to deselect a record.)

7. Align i-STAT 1 handheld and i-STAT Printer IR window or place in the Downloader or Downloader/Recharger attached to the i-STAT printer. Press the ⬛PRT key.

8. Do not move handheld or printer until printing is complete.

9. If printer is not powered from a wall outlet using the AC adapter, turn printer off.

PRINTOUT CONTENTS

Name of Test	i-STAT catridge type
Sample ID	Patient ID or quality test type and lot number of solution tested
Results	Results are printed with units as well as flags, reference ranges, and comment codes, if applicable
At Patient Temperature	If the patient's temperature was entered on the Chart Page, a second set of results is displayed for blood gases at the patient's temperature.
Sample Type	Sample type selected from Chart Page when sample is patient or proficiency test
Free Fields	Information entered into the Free Fields on the Chart Page when sample is patient or proficiency test
Time and Date	Time and Date when test was performed
Operator ID	Operator ID
Lot Number	Lot number of cartridge
Serial Number	Serial number of the handheld
Version	Handheld application software
CLEW	Standardization software

PRINTER CAUTIONS

- Use only a Rechargeable Battery pack purchased from Abbott Point of Care (List Number 04P74-03). Rechargeable battery packs not recommended by or purchased from Abbott Point of Care may be susceptible to overheating and could lead to a potential fire or burn hazard.

- Use only power adaptor and power supply (List Number 04P74-02) provided with the i-STAT Printer kit.

- Do not operate the printer without paper.

- Do not allow the power supply to become a trip hazard.

- Do not disturb the handheld or printer until printing is complete since this will interrupt the printout. If printing is interrupted, realign the printer and handheld or replace the handheld in the Downloader to resume printing. Note: if significant time has elapsed, some results may be missing from the printout. Reprint the results.

- If printed results appear inconsistent with a patient's clinical assessment, verify that the printed results match the data in the handheld. If the results do match, the patient sample should be retested using another cartridge. If they do not match, reprint the results. If the reprint still does not match the handheld data, the printer requires service and the printed results must not be used.

- Skin irritation, including caustic burns/injury, may occur following exposure to a leaking battery. Always wear gloves when handling a leaking battery, and do not permit a leaking battery to contact skin. Should skin exposure to a leaking battery occur, follow the first aid measures outlined in the MSDS Sheet for the Novacell nickel metal hydride battery.

- Fluorescent light sources can cause interference with communications sent to the i-STAT 1 Printer. When light from a fluorescent source of sufficient proximity or brightness has a direct path into the IR (Infrared Radiation) window of the i-STAT 1 Printer, the printer may fail to respond when records are sent for printing over a serial (wired) connection to a Downloader or Downloader/Recharger.

PRINTER TROUBLESHOOTING

PRINTER SYMPTOM	RECOMMMENDED ACTION(S)
Printer is not printing. The POWER indicator light is green/orange and the STATUS indicator light is green.	• Check that the results are displayed on the handheld, or that results have been selected from **List** under **Data Review.** • If printing directly from the handheld, check that the distance between the analyzer and printer is not too short or too long. • Perform printer self test to ensure that printer is functioning. Turn the printer off. While pressing the Paper Feed button, press down on the Power button until the printout begins, and then let go of both buttons. Ensure that the resulting printout is clear and complete.
Printer is not printing over a wired connection to a Downloader or Downloader/Recharger. The POWER indicator light is green/orange and the STATUS indicator light is green.	If the printer is in close proximity to a fluorescent light: • Reposition the printer or shield the IR window to prevent direct line-of-sight between the fluorescent light and the IR window. • Relocate the printer or fluorescent lamp to a greater distance from each other. • Turn off fluorescent lights within close proximity of the i-STAT 1 Printer when printing records via a serial connection. • Print directly from the handheld via an IR connection.

PRINTER SYMPTOM	RECOMMMENDED ACTION(S)
Printer is feeding paper, but nothing is printed.	Check that the paper is feeding from under the roll.
Printer is not printing and POWER indicator is red.	Battery needs to be recharged.
Printer POWER indicator does not illuminate when printer is turned on.	Battery needs to be recharged.
Printer is not printing and STATUS indicator is orange.	Printer is out of paper.
Printer is not printing and STATUS indicator is red.	Print head temperature is out of range. Printing will be inhibited until print head temperature returns to normal level.

CLEANING THE i-STAT PRINTER

Clean the external casing of the i-STAT Printer with a gauze pad moistened with any of the following approved cleaning agents:

- 10% bleach solution

- Isopropyl alcohol (IPA)

- PDI® Super Sani-Cloth® (solution of IPA, n-Alkyl dimethyl ethylbenzyl- and benzyl- ammonium chloride)

Rinse the printer casing using another gauze pad moistened with water and dry.

DO NOT IMMERSE THE PRINTER IN ANY FLUID, AT ANY TIME.

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i-STAT® TECHNICAL BULLETIN

i-STAT Printer Storage and Battery Check Notice

This Technical Bulletin provides supplemental instruction on i-STAT Printer Storage and assessing i-STAT Printer Rechargeable Battery charging status. This notice supersedes Technical Bulletin: i-STAT Printer Rechargeable Battery Notice (Art# 728730-xxB).

Printer Storage Instructions
When the Printer is not in use for an extended period:
- Keep the AC adapter connected to wall outlet and Printer, if possible.
- If AC power is unavailable, disconnect the i-STAT Printer Rechargeable Battery from the Printer. Failure to remove the battery may result in the inability for the battery to be charged following storage.

Battery Check
If the battery does not appear to accept charge during regular use, follow the instructions below to determine if the i-STAT Printer Rechargeable Battery is capable of charging:

1. Plug AC adapter into Printer and wall outlet and install i-STAT Printer Rechargeable Battery into the i-STAT Printer.
2. Make sure the Printer is turned off. Perform a self test on the i-STAT Printer by pressing the Paper Feed button then the Power button and holding both down until printing starts.
3. If the battery can be charged, the last line of the self test print out will state "Charging Enabled". If the battery cannot be charged, the last line will state "Charging Disabled".

If you have questions regarding the information in this Technical Bulletin or need additional support, please contact Abbott Point of Care Technical Support at 800-366-8020, option 1, or by email at techsvc@apoc.abbott.com.

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DATA MANAGEMENT 8

Introduction   The i-STAT System provides comprehensive data management capabilities to ensure that blood analysis results obtained at the patient bedside can be integrated into the hospital's various information systems. The Data Manager computer system is capable of receiving simultaneous transmissions from several different types of blood analysis instruments. The instruments may include, but are not limited to:

- ❑ i-STAT Portable Clinical Analyzer (PCA)
- ❑ i-STAT 1 Analyzer

This section describes the information management capabilities of the i-STAT System and how the components can be integrated to meet the needs of point-of-care data management.

Components   **The i-STAT 1 Analyzer**

With each cartridge use, the analyzer allows entry of:

- ❑ operator identification number
- ❑ patient identification number
- ❑ proficiency identification number
- ❑ simulator serial number
- ❑ cartridge lot number
- ❑ control lot number
- ❑ calibration verification lot number
- ❑ comment codes for patient and control results
- ❑ chart page information
    - sample type
    - patient temperature
    - FIO_2
    - free fields: three fields, up to 9 characters each

The Portable Clinical Analyzer

With each cartridge use, the analyzer allows entry of:

❑ operator identification number

❑ patient identification number

❑ chart page information

- patient temperature
- FIO_2
- free fields: three fields, up to 6 characters each
- sample type

The analyzer electronically attaches its serial number, the test date, and test time to the results.

The Data Manager

A validated and qualified Data Manager computer system may be purchased from Abbott Point of Care for use with the Central Data Station 5 software application. The end user also has the option to purchase the computer system from another hardware vendor. In those cases, Abbott Point of Care will provide a minimum requirement specification to ensure proper operation and functionality of the Central Data Station 5 software application.

Abbott Point of Care and its distributors can supply the following hardware:
- i-STAT Data Manager computer system and its peripherals
- IR Downloader (Serial and Network) and required components
- IR Link and required components

i-STAT Central Data Station Version 5 Software

This is i-STAT's primary data management application. It supports all blood analysis instruments mentioned above via a combination of serial and/or network communications.

Please see the "Central Data Station 5" section of this System Manual for additional information on installation, setup, and configuration of this application.

Data downloaded from the i-STAT 1 Analyzers can be viewed in separate Data Viewers for Results, QC Codes, Simulator, Unsent Records, Control Results, Calibration Verification Results, and Proficiency Results (external quality control).

Additional features include the ability to:

❑ view patient and quality results by patient identification number, operator identification number, date/time chronological order, location, department, or analyzer serial number.

❑ edit identification numbers associated with results (original numbers are automatically retained for reference)

❑ add comments to records

❑ send results (automatically or by manual selection) to another information system such as an LIS or HIS

- archive records

- export records to ASCII text files

- manage instruments

- manage operators

- manage inventory

- manage policy exceptions

- monitor operator competence

- monitor LIS entry exceptions

- monitor download compliance

Downloader and Downloader/ Recharger

The Downloader and Downloader/Recharger are available for use with ethernet cabling (network format) and direct wiring (serial format). The Network Downloaders convert serial data transmitted from the i-STAT 1 Analyzer via infrared transmission to TCP/IP, which then delivers the data to the Data Manager using the hospital's ethernet system.

Through a customizable feature, transmissions can be performed automatically when an analyzer is placed in the Downloader or Downloader/Recharger.

Please contact your i-STAT Support Representative for additional information related to specifications and configuration requirements for your facility.

IR Link

A Portable Clinical Analyzer communicates to the Data Manager via an Infrared Interface Link (IR Link). The IR Link converts infrared signals received from the analyzer to electronic signals, and passes them to the Data Manager. To transmit results, place an analyzer in the IR Link and press the star (*) key. A single IR Link can be used to collect results from a limitless number of Portable Clinical Analyzers, one at a time. Transmission time is usually less than 15 seconds.

LIS/HIS Interface

The Data Manager typically connects to the Laboratory or Hospital Information System. The user can manually select records to send or the Central Data Station application can be configured to automatically transmit records to the alternate system as they are received. There are four data transmission protocols available:

- AME (US only): this protocol is used to simulate manual keystrokes when connected to a hospital's LIS or HIS. This protocol is installed and configured only by i-STAT Interface Operations department.

- ASTM: Data transmission conforms to ASTM E1381-95 and E1394-97 standards. Specifications for this protocol can be obtained from your i-STAT Support Representative.

- HL7: This is a robust Electronic Data Interchange (EDI) interface. Data transmission conforms to HL7 v2.4 and is based upon the CIC observation Reporting Interface distributed by the National Committee for Clinical Laboratory Science (NCCLS) in the US under Document POCT-1-A. An activation key is required to use this protocol. Contact your i-STAT Support Representative to obtain this license key. This interface requires a receiver software from the LIS vendor.

- Data File: Formats the CDS file for third party use.

Standard Data Management Configuration

The figure below shows the standard i-STAT Data Management configuration. Downloaders, Downloader/Rechargers, and IR Links are placed in end-user departments and allow handheld analyzers to transmit results to the Data Manager.   The Data Manager then interfaces to the LIS/HIS.
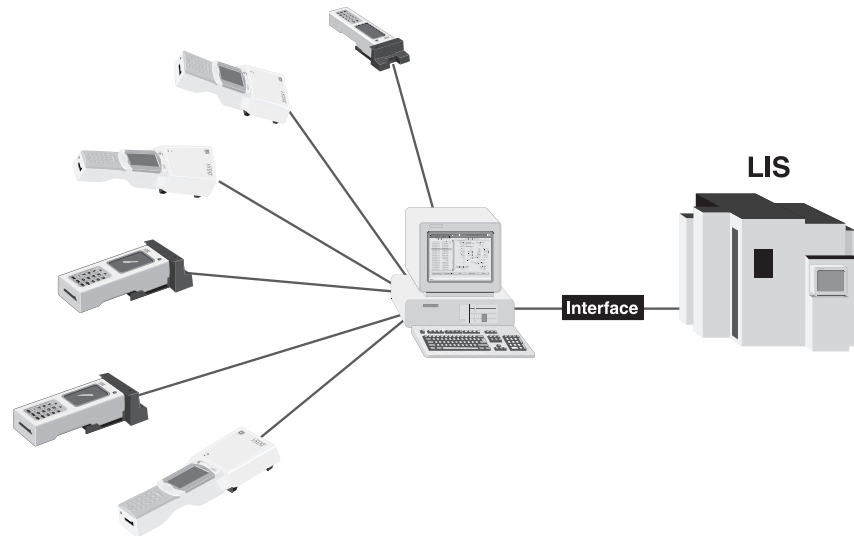
Connecting Components

There is only one option available for physically connecting remote Downloaders, Downloader/Rechargers, and IR Links to a Data Manager. That option is:

❑   Ethernet Connection

The i-STAT System connects terminal servers to Ethernet ports to allow a Local Area Network (LAN) or Wide Area Network (WAN) to transport data from a Downloader, Downloader/Recharger, or IR Link to the Data Manager using the TCP/IP protocol. Often, no additional wiring needs to be installed, but network ports or 'drops' may need to be installed in walls at appropriate locations. Also, power outlets will need to be available at each location in order to provide power to the Downloaders, Downloader/Rechargers or terminal servers. Using this method allows an unlimited number of Downloaders, Downloader/Rechargers, and IR Links to be connected to the Data Manager.

CUSTOMIZATION 9

Overview

This section describes the parameters that can be customized for site-specific testing requirements and the factory default settings. For the procedure to customize using the Central Data Station see the Central Data Station section of this manual. For the procedure to customize the analyzer directly through the keypad, see Customization in the i-STAT 1 Analyzer section of the manual. A customization profile consists of selections made from four major windows: Language, Unit Set, CLEW and Preferences. The Preferences Window consists of six additional tabs: Instrument, ID Entry, Test, Cartridge QC, Results, and Analyte Enable.

Caution

Handhelds that have been repaired and returned or replaced will have the factory settings as indicated by the DEFAULT0 customization profile name on the Customization screen (under the Administration Menu) of the handheld. These handhelds must be customized, if applicable, before being put into use. These handhelds will also have the current standard CLEW and application software (JAMS). If a different version of CLEW or application software is in use, it must be downloaded to these handhelds.

If location specific customization profiles are created, analyzers should not be moved from one location to another unless they are re-customized for the new location. This is especially important if "CPB Adjustment: Always" or "CPB Adjustment: Never" is included in a location-based customization profile. The CPB function adjusts hematocrit and hemoglobin results for the dilutional effect of pump fluid during cardiopulmonary bypass surgery. If a handheld customized for the CVOR as "CPB Adjustment: Always" is used for patients who are not on the pump, hematocrit results will be reported falsely high. If a handheld customized as "CPB Adjustment: Never" is used for patients who are on the pump, hematocrit results will be reported falsely low. For details on the CPB function, see the Theory section of this manual.

ANALYZER CUSTOMIZATION OPTIONS AND DEFAULT SETTINGS

Option	Description	Default	Comments
LANGUAGE WINDOW	Language for text: English, Japanese, German, Italian, Dutch, Spanish, French, Swedish, Portuguese, Danish, and Finnish	English	
UNIT SET WINDOW	Reporting units for results. Selected from predefined sets or by analyte.	Unit Set 00	See table below with 17 predefined unit sets. Unit Set 99 allows the name and units for each test to be defined individually. Note: Reference Ranges, Action Ranges, and Custom Reportable Ranges (if applicable) in the Preferences Window must be changed when changing units.
i-STAT 1 ANALYZER AND PHILIPS BAM CLEW WINDOWS	Standardization data. All non-expired versions listed.		The CLEW software has an expiration date. If an expired CLEW remains in a customization profile, a warning will be displayed.
i-STAT 1 SOFTWARE WINDOW	JAMS functionality data.		Users can remotely request a JAMS update for an i-STAT 1 Analyzer from the CDS. See the "Network Options for Updating the i-STAT 1 Handheld" Technical Bulletin in the "Care and Software Update" tabbed section of the i-STAT 1 System Manual for full details..
PREFERENCES WINDOW	Options and default settings are listed under six headings: Instrument, ID Entry, Test, Cartridge QC, Results, and Analyte Enable.		
STATNotes	Feature allows users to customize the Chart Page on their i-STAT 1 Analyzers in order to capture user-defined information such as ventilator settings.	CHART0	See the "i-STAT 1 Analyzer Chart Page Customization" Technical Bulletin for full details.
USE eVAS	This Feature can automatically determine if the results of a liquid QC test run on an i-STAT cartridge are within APOC's published quality control ranges.	Not enabled	See the "Liquid Quality Control Pass/Fail Customization on the i-STAT 1 Handheld" Technical Bulletin for full details.
USE OPERATOR LIST	4000 operator IDs can be stored in the analyzer along with certification start and end dates for cartridge testing.	Not enabled (no information stored)	Operator lists are created in the Operator Workspace on the Central Data Station. This check box cannot be enabled if the Operator List is empty in the Operator Workspace for all Departments (other than the one labeled "Unassigned").

PREFERENCE WINDOW: FOR INSTRUMENT OPTIONS

Option	Description	Default	Comments
PASSWORD	0-5 digit password to access Set Clock, the Change function in Customization, and Utility under the Administration Menu.	No password	Password protection for the Set Clock function can be enabled or disabled. See below.
DATE FORMAT	mm/dd/yy or dd/mm/yy	mm/dd/yy	For Clock Set function only.
INACTIVITY TIMEOUT	Number of seconds after a result is displayed and no operator intervention that an analyzer will turn off. Allowable range is 45 to 1620 seconds.	120 seconds	
SOUND	If enabled, the analyzer will emit a beep after each successful key press, when results are ready or when a Quality Check message is displayed.	Beep enabled	If Sound is disabled, the analyzer will only beep after a successful barcode entry.
ENABLE WIRELESS CUMMUNICATION (U.S. CUSTOMER USE ONLY)	Enable the wireless functionality in an i-STAT 1 Wireless handheld	Not Enabled	See the "Procedure for Using the i-STAT 1 Wireless Analyzer" Technical Bulletin for full details.
AUTO TRANSMIT	Handheld transmits results when placed in Downloader or Downloader/Recharger.	Enabled	
MEMORY FULL ACTION	Not enabled: over-write the oldest record without warning. Enabled: Warn user (start-up warning) or Lockout (testing disabled until upload occurs).	Not enabled	Memory Full refers to when the unsent records as recorded on the Analyzer Status screen reaches 1000. Uploading does not erase the data from the handheld's memory.
BATCH MODE TIMEOUT	Not active at this time.		
DISPLAY PASSWORD FOR CLOCK PAGE	The default setting is enabled. However it may be useful to disable password protection for the clock page in the Spring and Fall when clocks are set forward and backward one hour.	Enabled	
SYNCHRONIZE CLOCK TO CDS	Will synchronize or update the real time clock in the i-STAT 1 handheld to the Central Data Station's clock at the time of each download.	Not Enabled	This eliminates the need to reset the handheld's clock at the beginning and end of Daylight Savings Time.
APPLY OPERATOR LIST TO VIEWING STORED PATIENT RECORDS	Requires operator to enter their operator ID number to access stored patient results on the i-STAT 1 handheld.	Not Enabled	This option can help a facility comply with patient privacy regulations.
LIMIT NUMBER OF RECORDS IN TRANSMIT ALL	Allows the user to apply a date range limit to the Transmit All function in the i-STAT 1 handheld	Not Enabled	This will prevent operators from sending older patient records that may have already been deleted from the Central Data Station.
UPLOAD SCHEDULE	Options are Off, or every X hours, where X can be 1 to 65535 hours. If enabled, the behavior of the analyzer if the schedule is not met can be specified. Behavior Options are: Warn User (start-up warning message) or Lockout (testing disabled until upload occurs).	Off: no warning or lockout.	If no upload schedule is specified and the Memory Full warning is ignored and Auto-transmit disabled, data will eventually be overwritten. However, if a handheld has not been used and the upload interval is exceeded, this handheld will be inoperable if the lockout option is used.

PREFERENCE WINDOW: FOR OPERATOR AND PATIENT ID OPTIONS

Option	Description	Default	Comments
OPERATOR ID	Minimum and maximum allowed operator ID length (scanned or manually entered)	Min = 0 Max = 15	If operator IDs are a fixed length, the min. and max. settings should both be equal to the ID length.
REPEAT ID ENTRY	Operator must enter ID twice. Handheld prompts operator to start again if IDs do not match.	Enabled: repeat required	This option can be set for manual and/or scanned ID Entry.
INCLUDE ID ON PRINTOUT	Enables/Disables printing of operator IDs on printouts from the Martel or i-STAT printer.	Enabled	Disabling the printing of operator IDs can prevent uncertified operators from learning the IDs of certified operators.
BARCODE OPTIONS	The type of barcodes used for Operator ID. See table below.	All barcode types	
MANUAL ENTRY CHECK DIGIT	Options are None, ISBN Modulus 11 Check, and IBM Modulus 10 Check.	None	Check digit algorithms are given in HL7 Specification, Section 2.9.5.3
INVALID OPERATOR	Behavior of handheld when Operator ID not in stored list or certification date expired Options are: Not enabled (continue without warning), Warn User (prompt to continue), and Lockout (block testing until a valid Operator ID is scanned/entered).	Continue without warning	This option should not be enabled if the Use Operator List option is disabled.

Separate Actions can be chosen for Certification Expired or Operator Not On List. |
EXPIRATION NOTIFICATION	Allows a System Administrator to define a time period (1-255 days) in which the operator will be notified by a message on the i-STAT 1 handheld display of their competency expiration date.	Off	See the Technoical Bulletin "Operator Competency Notification on the i-STAT 1 Handheld" for full details.
PATIENT ID	Minimum and maximum allowed patient ID length (scanned or manually entered)	Min = 0 Max = 15	If ID numbers are a fixed length, the min. and max. settings should both be equal to the ID length.
REPEAT ID ENTRY	Operator must enter patient ID twice. Analyzer prompts operator to start again if IDs do not match.	Repeat ID enabled	This option can be set for manual and/or scanned ID entry.
PATIENT ID RECALL	Operator can recall last patient ID when analyzer prompts for Patient ID.	Enabled	The most recent patient ID is recalled by pressing the → key.
BARCODE OPTIONS	The type of barcodes used for Patient ID. See table below.	All barcode types	
MANUAL ENTRY CHECK DIGIT	Options are None, ISBN Modulus 11 Check, and IBM Modulus 10 Check.	None	Check digit algorithms are given in HL7 Specification, Section 2.9.5.3

PREFERENCE WINDOW: for Test Options

Option	Description	Default	Comments
AUTO-CHART PRESENTATION	If enabled, the Chart Page will be displayed automatically.	Not enabled: operator must press the → key to display the Chart Page.	If any information on the Chart Page is mandatory for the site, Auto-Chart Presentation is recommended.
CARTRIDGE PATIENT TEST	The behavior for the following features is set by the analyzer firmware and no longer requires customization: • Require Information before Running Cartridge • Enter Lot Number • Scan Cartridge Barcode Third Party Result Output and Require Analyzer to be in Downloader: These two options were instituted for the release of the RIBS data integration feature. Please see the "The RIBS (Results Integration at the Bedside) Feature for the i-STAT System" Technical Bulletin for full details. **These options SHOULD NOT be activated by users until the data integration process is complete, as misconfiguring your analyzers using these features can cause testing to be disabled.**	Not enabled	
PATIENT TEST COMMENT CODE	Options are: No prompt or prompt as follows: • Prompt for Comment Code, All Results in Range (action range). Comment Code can be optional (Allow no Comment) or mandatory (Require Comment). • Prompt for Comment Code, Any Result out of Range (action range). Comment Code can be optional (Allow no Comment) or mandatory (Require Comment). • A comment code of up to 3 characters is allowed.	No prompt	Care should be taken to select combinations that make sense. In the case of a missed required Comment Code, the results will be stored and "_ _ _" will be entered as the Comment Code.
SAMPLE TYPES FOR CARTRIDGE	Drop down menus for each sample type allow the six sample types to be re-ordered or changed. Up to 4 user-definable characters are allowed for each sample type.	1-ART 4-CAP 2-VEN 5-CORD 3-MIX 6-OTHR	The sample type is stored with the test record and is included on the printout from the portable printer and in the record in the Central Data Station.
CHART PAGE	Any item on the Chart Page can be deleted by clicking off the check mark in the Display column or be made mandatory by clicking a check mark in the Mandatory column. If any item is set as mandatory, the Chart Page will be displayed automatically after the Patient ID is entered. The items on the Chart page can also be rearranged by holding down the left mouse button and dragging the item to another location.	All items set to not mandatory.	

PREFERENCE WINDOW: for Cartridge QC – Electronic QC Settings

Option	Description	Default	Comments
EXTERNAL SIMULATOR SCHEDULE	Options are Off (no prompt), an interval of specified hours (1 to 65535 hours), or an interval of specified patient tests (up to 99999). The behavior of the analyzer if the schedule is not met can also be specified: Warn or Lockout (testing disabled until Simulator used).	No prompt	For the quality control of i-STAT analyzers, i-STAT recommends the use of the Electronic Simulator. i-STAT's recommendation for the frequency of the Electronic Simulator is once every 24 hours. More frequent use or use according to number of patient tests may be required by accreditation and regulatory bodies.
INTERNAL SIMULATOR SCHEDULE	Time interval when the internal Electronic Simulator test will be run. Options are Off; an interval of specified hours (1 to 65535 hours); 8/24 (every 8 hours for blood gases, coagulation, hematocrit and immunoassays, and every 24 hours for other tests); an interval of specified patient tests (up to 99999). The behavior of the analyzer if the simulator test fails can also be specified. If the Schedule Option Lockout is selected, the analyzer will continue to perform the simulator test and will continue to display "FAIL" on subsequent cartridges until the test passes. If Lockout is not selected, the simulator test will not be initiated again until next scheduled time.	Interval 24 hours. Lockout	

PREFERENCE WINDOW: for Cartridge QC – Liquid QC Settings

Option	Description	Default	Comments
CONTROL PASS/FAIL DETERMINATION	Describes the way in which the System Administrator will determine the acceptability of liquid QC results. Options are: None: Disables the QC Pass/Fail and QC Schedule feature. Automatic via EVAS: Choosing this option indicates that the handheld will automatically determine whether the liquid QC run passed or failed, based upon QC ranges contained on an electronic Value Assignment Sheet (eVAS) file downloaded into the i-STAT 1 handheld. Manual: The user will manually compare the liquid QC results to a Value Assignment Sheet downloaded or printed from the Abbott Point of Care (APOC) website at www.abbottpointofcare.com/valsheets and indicate on the handheld whether the QC run passed or failed.	None	See the Technical Bulletins "Liquid Quality Control Schedule and Lockout Customization on the i-STAT 1 Handheld" and "Liquid Quality Control Pass/Fail Customization on the i-STAT 1 Handheld" for full details.

CONTROL TEST SETTINGS	If the System Administrator wants users to enter a Comment Code when liquid QC results are in-range, out-of-range, or under both situations, they would check the appropriate box and then use the drop down menu to select whether entering the comment code is optional (Allow no comment) or Required (Require Comment).	Disabled	Comment Code options can only be selected if one of the Control Pass/Fail Determination methods has been selected.
CONTROL RESULTS DISPLAY FORMAT	Options are: Numeric: liquid QC results are displayed in numeric format. Suppressed: the following symbol "<>" is displayed next to each liquid QC test name in place of the quantitative (numeric) results.	Numeric	The "Suppressed" option should only be chosen if "Automatic via EVAS" is chosen for the liquid QC Pass/Fail Determination.
APOC FLUID LOT ENTRY METHOD	Options are: Scan or Enter: allows the user the option of manually entering the liquid QC lot information into the handheld, or scanning it from the barcode on the quality control vial being tested. Scan only: the fluid lot information must be entered by scanning the barcode on the vial being tested.	Scan or Enter	
SCHEDULE STATUS	Displays the status of previously defined Liquid QC Schedules	Off	

PREFERENCE WINDOW: FOR CARTRIDGE QC - LIQUID QC SCHEDULE (1, 2, OR 3)

Option	Description	Default	Comments
QC FREQUENCY	Describes the frequency at which the System Administrator wants the liquid QC run under this schedule. Options are: Off: Disables the selected QC Schedule Daily Weekly: A particular day of the week (e.g. every Monday) Monthly: A particular day of the month (e.g. the second Tuesday of the month)	Off	See the Technical Bulletin "Liquid Quality Control Schedule and Lockout Customization on the i-STAT 1 Handheld" for full details.
QC TIME	The QC Time sets the time when the QC Cycles (a test run in the Control pathway consisting of a QC cartridge and a corresponding QC fluid) will begin to count toward satisfying the QC test profiles, i.e. when QC will become "due to start". The Grace Period is the period of time, starting from the Due Time, during which the QC test profile must be completed before the corresponding cartridge set is locked out.	Disabled	A QC Time can only be chosen if QC Frequency has been activated. Use the 24 hour clock designation to indicate the time when QC is due. For example, if QC will be due at 2 pm, enter 14:00 for the time. Enter the Grace Period in hours: • Up to 23 hours for daily schedules • Up to 167 hours for weekly schedules, and • Up to 255 hours for monthly schedules. The minimum Grace Period is one hour for any schedule type.

APPLY QC SCHEDULE TO	The months of the year to which this schedule will apply. Options are: All months Selected Months: Check the box next to the months to which this schedule will apply.	All months	
CARTRIDGE QC PROFILE	The System Administrator defines a QC cartridge set consisting of: A QC cartridge type (i.e. the cartridge type to be test with specified liquid QC fluids during the QC procedure), as well as Any number of dependent cartridge types (i.e. associated cartridge types that will be enabled by the handheld if the QC requirements for a given cartridge set are met on that handheld). The System Administrator then associates the defined cartridge set with up to six (6) specific QC fluids.	Disabled	A Cartridge QC Profile can only be edited or created if QC Frequency has been activated. See the Technical Bulletin "Liquid Quality Control Schedule and Lockout Customization on the i-STAT 1 Handheld" for full details on defining a Cartridge QC Profile.

PREFERENCE WINDOW: FOR RESULTS REPORTING OPTIONS

Option	Description	Default	Comments
REFERENCE RANGES	Reference ranges can be defined for each test. The ranges will be depicted as tic marks on the bar graphs on the result pages. There are no bar graphs for blood gas, coagulation, and immunoassay tests.	Ranges are listed in the Cartridge and Test Information sheets.	Ranges will be displayed on the Customization screen of the handheld under the Administration Menu. Only one range is allowed for each test in a particular handheld. However, different customization profiles can be set up in specific handhelds used for specific patient populations. Care should be taken to enter the same units as selected in the Unit Set Window.
ACTION RANGES	High and low action ranges can be defined for each test.	Disabled (-99999.9 to 99999.9)	**Care should be taken to enter Action Ranges within the reportable ranges of the tests.** **Care should be taken to enter the same units as selected in the Unit Set Window.**
CUSTOM REPORTABLE RANGES	High and low custom Reportable Ranges can be defined for each analyte (except ACT).	Disabled (-99999.9 to 99999.9)	See the "Reportable Range Customization on the i-STAT 1 Handheld" Technical Bulletin for full details.
PRINT REFERENCE RANGES	Reference Ranges can be printed with results. Ranges will print only if the record to be printed is stored with the active Preference set in the handheld.	Disabled	The active Preference set in the handheld is listed as "Custom" on the Analyzer Status page and the Preference set stored with the record is displayed on the Chart Page when the record is recalled and is printed with the results.

OPERATOR TEST SELECTION	Requires the operator to select tests to be reported from a cartridge test panel.	Disabled	This option facilitates compliance with Medicare/Medicaid regulations in the USA.
ACT OPTIONS (i-STAT 1 Analyzer Only)	The user can select between the current 37° (PREWRM) result calibration and a new "NON-PREWARM" (ambient temperature) result calibration for both Celite ACT and Kaolin ACT cartridges.	PREWRM for both cartridge types.	Pleas see the Technical Bulleti "ACT Test Result Calibration Options: PREWARMED vs. NON-PREWARMED Result Calibration Modes for the i-STAT 1 Analyzer" for full discussion.
HEMATOCRIT OPTIONS	Reference anticoagulant used to calculate hematocrit result: K3EDTA or K2EDTA/Heparin/None. (NaEDTA is included in this option and None means no anticoagulant.) CPB options are: 1. **Prompt:** asks user whether to apply CPB compensation when cartridge includes hematocrit sensor. 2. **Never:** CPB correction is never applied when running a cartridge with a hematocrit sensor.. 3. **Always:** apply CPB correction every time it runs a cartridge with a hematocrit sensor.	K3EDTA Prompt CPB	See Theory section in this manual for explanation of CPB. Analyzers can be customized by location. Analyzers customized for "CPB: Always" should not be used for reporting Proficiency Testing results..
DECIMAL SEPARATOR	Select comma (,) or period (.)	Period	
BASE EXCESS CALCULATION	Select Base Excess of Extracellular Fluid (BEecf) or Base Excess of Blood (BEb).	BEecf	See Cartridge and Test Information sheet for $P\text{CO}_2$ for formulas.

PREFERENCE WINDOW: for Analyte Enable

Option	Description	Default	Comments
APPLY GLOBALLY	Test(s) can be disabled for all cartridge types. To enable/disable a particular analyte on all cartridge types, simply check/uncheck the box next to the analyte name in the Apply Globally section.	All tests enabled.	The global selection takes precedence over the cartridge type selection.
APPLY BY PANEL	Test(s) can be disabled for individual cartridge types. To enable/disable a particular analyte on a specific cartridge type, make sure the analyte is first checked under the Apply Globally section. Then click on the cartridge type under the Apply by Panel section, and then check/uncheck the box next to the analyte name.	All tests enabled for all cartridge types.	

PREFERENCE WINDOW: FOR BARCODES

Option	Description	Default	Comments
ID BARCODES *	The user can select any or all of the following as valid barcode formats for both the operator and patient ID: • I2 of 5 • Code 128 • Codabar • Code 93 • Code 39 • EAN 8, EAN 13	All barcode types	Barcode type Code 128 will support USS 128 and UCC/EAN 128, but not ISBT 128.
I2 OF 5 OPTIONS	No Check Digit USS Check Digit OPCC Check Digit	USS Check Digit	
CODE 39 OPTIONS	Check Digit or No Check Digit Alphanumeric or Full ASCII	Check Digit, Full ASCII	
TRUNCATE DIGITS	User can select how to truncate digits from a scanned operator and/or patient ID: First: enter number of leading characters to be stripped from the barcode. Last: enter number of trailing characters to be stripped from the barcode.	No truncation	The analyzer will accept up to 15 characters for operator and patient IDs.

* Note: For fields other than Operator and Patient ID, only the default setting for the barcode type can be scanned. These are:

• Code I2 of 5 with USS Check Digit
• Code 39 Full ASCII with Check Digit

UNIT SETS 17 PREDEFINED UNIT SETS ARE AVAILABLE IN THE UNIT SET WINDOW. THERE IS ALSO A UNIT SET 99 THAT CAN BE USED TO SELECT THE NAME AND UNIT FOR EACH TEST. THE DEFAULT UNIT SET IS 00

RESULT	0	1	2	3	4	5	6	7	8	9	10
Na/K/Cl *	mmol/L	mmol/L	mmol/L	mmol/L	mEq/L	mmol/L	mmol/L	mmol/L	mmol/L	mmol/L	mmol/L
BUN	mg/dL										
Urea		mmol/L	mmol/L	mg/dL	mg/dL	mg/dL	mg/dL	mmol/L	mmol/L	mmol/L	mmol/L
Crea	mg/dL	μmol/L	μmol/L	mg/dL	mg/dL	mg/dL	mg/dL	μmol/L	μmol/L	μmol/L	μmol/L
Glu	mg/dL	mmol/L	mmol/L	mmol/L	mg/dL	mg/dL	mg/dL	mmol/L	mmol/L	mmol/L	mmol/L
Lac	mmol/L	mmol/L	mmol/L	mmol/L	mmol/L	mmol/L	mmol/L	mmol/L	mmol/L	mmol/L	mmol/L
pH											
PCO2/PO2	mmHg	kPa	kPa	mmHg	mmHg	mmHg	mmHg	kPa	mmHg	mmHg	kPa
Hct	%PCV		%PCV	%PCV	%PCV	%PCV	%PCV	%PCV			
Hb	g/dL	g/L	g/L	g/dL	g/dL	g/dL	g/dL	mmol/L	g/L	g/dL	g/dL
HCO3/BE	mmol/L	mmol/L	mmol/L	mEq/L	mmol/L	mmol/L	mEq/L	mmol/L	mmol/L	mmol/L	mmol/L
iCa	mmol/L	mmol/L	mmol/L	mmol/L	mmol/L	mmol/L	mmol/L	mmol/L	mmol/L	mmol/L	mmol/L
sO2	%	%	%	%	%	%	%	%	%	%	%

RESULT	11	12	13	14	15	16
Na/K/Cl	mmol/L	mmol/L	mmol/L	mmol/L	mEq/L	mmol/L
BUN		mg/dL			mg/dL	
Urea	mmol/L		mmol/L	mmol/L		g/L
Crea	μmol/L	mg/dL	μmol/L	μmol/L	mg/dL	μmol/L
Glu	mmol/L	mg/dL	mmol/L	mmol/L	mg/dL	g/L
Lac	mmol/L	mmol/L	mmol/L	mmol/L	mmol/L	mmol/L
pH						
PCO2/PO2	kPa	mmHg	mmHg	mmHg	mmHg	mmHg
Hct		%PCV	%PCV	%PCV	%PCV	%PCV
Hb	g/dL	g/dL	g/dL	mmol/L	g/dL	g/dL
HCO3/BE	mmol/L	mmol/L	mmol/L	mmol/L	mEq/L	mmol/L
iCa	mg/dL	mg/dL	mmol/L	mmol/L	mEq/L	mmol/L
sO2	%	%	%	%	%	%

* Also, TCO2 and Anion Gap, except:

    03 TCO2 mEq/L

    04 TCO2, Anion Gap mmol/L

    06 Anion Gap, HCO3, BE mEq/L

Note: There are no units for pH or for hematocrit when reported as decimal fraction

Note: See Cartridge and Test Information sheets for ACT, PT/INR, cTnI, CK-MB, ß-hCG, and BNP units.

i-STAT®
TECHNICAL BULLETIN

REPORTABLE RANGE CUSTOMIZATION ON THE i-STAT® 1 HANDHELD

OVERVIEW

As part of the on-going READi initiative (**R**esponds, **E**nhances, **A**nd **D**elivers **I**nnovation), Abbott Point of Care (APOC) has released a new Custom Reportable Range feature for the i-STAT® 1 handheld. This new feature allows a system administrator (e.g., Point of Care Coordinator or Laboratory Administrator) to limit the displayed Reportable Range of each i-STAT analyte (except for ACT Celite or ACT Kaolin) on the i-STAT 1 handheld, on printouts, and in the electronic test record sent to the Data Manager.

The display ranges on the i-STAT 1 handheld are currently set to factory default values. While system administrators are not able to broaden the display range wider than the default values, this new Custom Reportable Range feature enables them to restrict the display range to custom values to meet clinical and regulatory needs. For example, system administrators may wish to limit the display ranges to values that have been verified using calibration verification materials.

GENERAL NOTES AND CONSIDERATIONS

1. The Custom Reportable Range feature is only available on the i-STAT 1 handheld, and not the i-STAT Portable Clinical Analyzer (i-STAT 200 series model).

2. In order to use the Custom Reportable Range feature, users must have the i-STAT 1 handheld and either the Central Data Station Version 5 or i-STAT/DE data management applications. This feature is not customizable through the i-STAT 1 handheld keypad.

3. **Changes to the reportable range may require a change to the LIS interface. Please contact your interface vendor.**

CAUTIONS

1. Narrowing reportable ranges from the default settings may reduce the clinical utility of test results. Therefore, ensure all Custom Reportable Ranges meet the clinical requirements for testing at your facility.

2. The Custom Reportable Range feature applies to the Patient, Proficiency, and Control test pathways on the i-STAT 1 handheld, but not to the Cal Ver pathway.

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Note: When running controls, if the handheld is customized for User Defined Reportable Ranges <u>and</u> Auto Pass/Fail detection, the handheld will display the control result based upon the customized Reportable Range setting, but will base the Auto Pass/Fail determination on the measured value, irrespective of the Reportable Range settings.

3. Narrowing the reportable range of certain tests may affect the presentation of other dependent test results. In the table below, if any of the results in the first column are outside the reportable range, the dependent test results listed in the second column will be suppressed (displayed as <>).

Reportable Range Limitations	
Test (Outside the Reportable Range)	**Dependent Suppressed Tests (displayed as <>)**
Na	K, Cl, BUN, Anion Gap, Hgb, Hct
Hct	Cl, BUN, Anion Gap, Hgb
PCO$_2$	TCO$_2$, Anion Gap, Base Excess, HCO$_3$, sO$_2$
pH	TCO$_2$, Anion Gap, Base Excess, HCO$_3$, sO$_2$
HCO$_3$	TCO$_2$, Anion Gap, Base Excess, sO$_2$
Cl	Anion Gap
K	Anion Gap
TCO$_2$	Anion Gap
PO$_2$	sO$_2$
PT/INR	PT WBT

MINIMUM SOFTWARE REQUIREMENTS

The minimum handheld and data management requirements for use of the Custom Reportable Range feature are summarized as follows:

System Component	Minimum Software Requirements
i-STAT 1 handheld	≥ JAMS132
Central Data Station Version 5.x	≥ Version 5.26a
i-STAT/DE	≥ Version 2.3

Art: 730009-00C   Rev. Date: 09-Aug-13

1. Click on **Main** → **Open Administration Function** → **Customization**

2. Type in your password and click **OK**. The default password is the word *istat*.
   Note: Abbott Point of Care Inc. recommends changing the default password.

3. Make sure the **"Enable Customization"** box has a check mark in it.

Also, make certain that the **Enable Updates** box is checked for the particular location to which the i-STAT 1 handheld is assigned.

4. If the location where this handheld is assigned has a check mark under **Use Default Profile**, under the **Default customization profile:** column, double click the alphanumeric code under **Preferences**. Otherwise, double click the alphanumeric code under the **Preferences** column for the specific location to which this handheld is assigned.

5. Once the **Preferences** window opens, click on the **Results** tab.

6. In the **Custom Reportable Ranges** section, scroll down to the analyte row which you wish to customize, and click on the corresponding Low or High box for that analyte. Type in the customized Reportable Range value for the Low or High Reportable Range. Repeat step 6 until all customized Reportable Range data have been entered.

Analyte	Reference Ranges		Action Ranges		Custom Reportable Ranges	
	Low	High	Low	High	Low	High
Na	138	146	-99999.9	99999.9	-99999.9	99999.9
K	3.5	4.9	-99999.9	99999.9	-99999.9	99999.9
Cl	98	109	-99999.9	99999.9	-99999.9	99999.9
BUN	8	26	-99999.9	99999.9	-99999.9	99999.9
Creat	0.6	1.3	-99999.9	99999.9	-99999.9	99999.9
Glu	70	105	-99999.9	99999.9	-99999.9	99999.9
Lac	0.36	1.25	-99999.9	99999.9	-99999.9	99999.9
AnGap	10	20	-99999.9	99999.9	-99999.9	99999.9
Hct	38	51	-99999.9	99999.9	-99999.9	99999.9

Selection
DEFAULT0

Description

Default Values

Note 6.1: All analytes listed in the table can be customized, with the exception of ACT Celite and ACT Kaolin results.

Note 6.2: Users may customize either the upper or lower limit of the Reportable Range, or both. Analytes in the Custom Reportable Ranges table that are left with the default cell value of **-99999.9** or **+99999.9** will continue to report the default Reportable Ranges listed in the Cartridge and Test Information Sheet section of the i-STAT 1 System Manual.

Note 6.3: Users may not broaden the displayed Reportable Range beyond the default values. If a value outside the default Reportable Range is entered, the handheld will continue to display the default Reportable Range values for that analyte.

Note 6.4: Users should enter range values consistent with the resolution of the analyte/unit being customized. For example, since sodium results are reported in whole numbers on the handheld, users should select customized range values in whole numbers.

Note 6.5: Users are responsible for ensuring that the entered Reportable Range values are appropriate for the Unit Set in use in the handheld.

7. Click **OK** and answer **YES** to the question about changing the Preferences.

8. Download the handheld(s) to the CDS from a downloader in the location to which the handheld is assigned. This action will upload the chosen customization features into the handheld. Repeat step 8 for all handhelds from the same location to be customized. To customize handhelds from other locations for the same features, return to step 1.
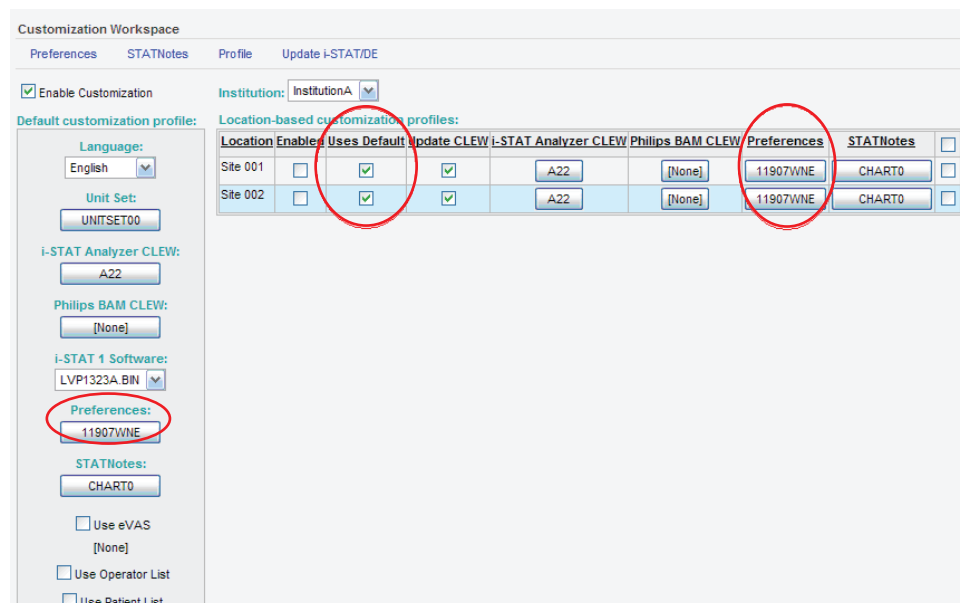
1. Access the Customization Workspace

    • RALS-Plus Users:

        ○ RALS-Plus application, pick i-STAT from the drop-down menu.

        ○ Click on **Device Customization**.

    • PrecisionWeb Users::

        ○ Enter the DE i-STAT Customization Workspace.

2. Make sure the **"Enable Customization"** box has a check mark in it.

    Also, make certain that the **Enabled** box is checked for the particular location to which the i-STAT 1 handheld is assigned.

3. If the location where this handheld is assigned has a check mark under **Uses Default**, under the **Default customization profile:** column, double click the alphanumeric code under **Preferences**. Otherwise, double click the alphanumeric code under the **Preferences** column for the specific location to which this handheld is assigned.

4. Once the **Preferences** window opens, click on the **Results** tab.

5. In the **Custom Reportable Ranges** section, use the page numbers below the table to find the analyte row which you wish to customize, and click **Edit** at the right end of that row. Type in the customized Reportable Range value for the Low or High Reportable Range, and then click **Update**. Repeat step 5 until all customized Reportable Range data have been entered.

		Reference Ranges		Action Ranges		Custom Reportable Ranges		
Analyte	Low	High	Low	High	Low	High		
Na	138	146	-99999.9	99999.9	-99999.9	99999.9	Edit
K	3.5	4.9	-99999.9	99999.9	-99999.9	99999.9	Edit
Cl	98	109	-99999.9	99999.9	-99999.9	99999.9	Edit
BUN	8	26	-99999.9	99999.9	-99999.9	99999.9	Edit
Crea	0.6	1.3	-99999.9	99999.9	-99999.9	99999.9	Edit

(DEFAULT0 — Description — Default Values)

Note 5.1: All analytes listed in the table can be customized, with the exception of ACT Celite and ACT Kaolin results.

Note 5.2: Users may customize either the upper or lower limit of the Reportable Range, or both. Analytes in the Custom Reportable Ranges table that are left with the default cell value of **-99999.9** or +99999.9 will continue to report the default Reportable Ranges listed in the Cartridge and Test Information Sheet section of the i-STAT 1 System Manual.

Note 5.3: Users **may not** broaden the displayed Reportable Range beyond the default values. If a value outside the default Reportable Range is entered, the handheld will continue to display the default Reportable Range values for that analyte.

Note 5.4: Users should enter range values consistent with the resolution of the analyte/unit being customized. For example, since sodium results are reported in whole numbers on the handheld, users should select customized range values in whole numbers.

Note 5.5: Users are responsible for ensuring that the entered Reportable Range values are appropriate for the Unit Set in use in the handheld.

6. Click **OK** and answer **OK** to the question about changing the Preferences.

Message from webpage

? Do you want to change preferences?

OK   Cancel
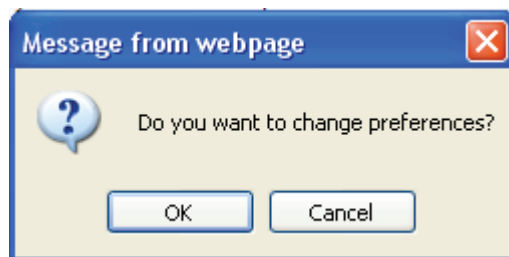
7. Download the handheld(s) to i-STAT/DE from a downloader in the location to which the handheld is assigned. This action will upload the chosen customization features into the handheld. Repeat step 7 for all handhelds from the same location to be customized. To customize handhelds from other locations for the same features, return to step 1.

CONFIRMING THAT THE CUSTOM REPORTABLE RANGES HAVE BEEN TRANSFERRED TO THE i-STAT 1 HANDHELD FROM CDS VERSION 5 OR i-STAT/DE

1. Power on the i-STAT 1 handheld and press **MENU** once to get to the Administration Menu.

2. Press **4 -Customization.**

```
14:36 26JUL11

Administration Menu

1-Analyzer Status
2-Data Review
3-Quality Tests
4-Customization
5-Set Clock
6-Transmit Data
7-Utility
```

3. Press **1-View.**.

```
Customization
11726BP9

1-View
2-Change
```

4. Press **5-Results**.
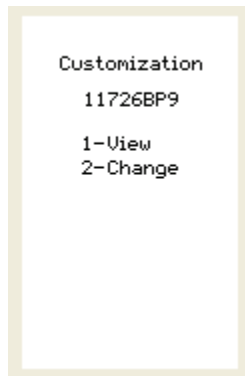
```
View
Customization

1-Analyzer
2-ID Entry
3-Patient Tests
4-QC Tests
5-Results
```

5. Press **2-Display Ranges**.

```
          View
      Customization
        Results

   1-Act/Ref Ranges
   2-Display Ranges
   3-Units
   4-Options
```

6. View the displayed Reportable Ranges. If the analyte customized for Reportable Ranges does not appear on the first page of the screen, press the → key to find the page containing the analyte which has the customized display range and view the customized values. In the example below, the sodium Reportable Range has been customized to 110-170 mmol/L.

```
          Results
      Units and Ranges
    Cl mmol/L
    Dsp 65/140

    K mmol/L
    Dsp 2.0/9.0

    Na mmol/L
    Dsp 110/170

    BUN mg/dL
    Dsp 3/140

    iCa mmol/L
    Dsp 0.25/2.50

          Page   ➡
```

i-STAT® TECHNICAL BULLETIN

LIQUID QUALITY CONTROL SCHEDULE AND LOCKOUT CUSTOMIZATION ON THE i-STAT® 1 HANDHELD

OVERVIEW

As part of the on-going READi initiative (**R**esponds, **E**nhances, **A**nd **D**elivers **I**nnovation), Abbott Point of Care (APOC) has released a new Liquid Quality Schedule and Lockout feature for the i-STAT® 1 handheld. This new feature allows a system administrator (e.g. Point of Care Coordinator or Laboratory Administrator) to define a liquid quality control plan for their i-STAT 1 handhelds and enables them to enforce quality control (QC) compliance by invoking automatic lockout of patient and proficiency testing pathways if QC requirements in the plan are not fulfilled. By default, the feature is turned off.

This feature can be used in conjunction with the new Liquid QC Pass/Fail customization to automate and manage liquid quality control testing on the i-STAT 1 handheld. Please see the Technical Bulletin "Liquid Quality Control Pass/Fail Customization on the i-STAT 1 Handheld" for more information.

Functionality
Previously, system administrators had to "manually" manage and enforce QC requirements for the i-STAT 1 System, since no automated liquid QC lockouts were provided. With this new customization feature, the system administrator can define a customized QC plan that includes:

- which cartridge types and liquid QC fluids must be run,
- which cartridge types are enabled by running the liquid QC, and
- under what schedule the liquid QC is to be performed.

A. QC Profile
Using the Customization Workspace in the i-STAT CDS application or i-STAT/DE, the system administrator defines a number of QC *cartridge sets*, consisting of:

- a *QC cartridge type* (i.e. the cartridge type to be tested with specified liquid QC fluids during the QC procedure), as well as
- any number of *dependent cartridge types* (i.e. associated cartridge types that will be enabled by the analyzer if the QC requirements for a given cartridge set are met on that analyzer. A QC cartridge set is allowed to have zero dependent cartridges).

Note: A QC cartridge in one QC cartridge set cannot be a dependent cartridge in another QC cartridge set within the same schedule, but it can be a dependent cartridge in a QC cartridge set belonging to a different schedule.

The system administrator also creates a *QC test profile* by associating the defined cartridge set with up to six (6) specific QC fluids (i.e. specified types and levels of liquid control fluid). All APOC control fluids as well as three generic (user-defined) fluids are available for selection in the QC test profile.

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B. QC Scheduling

The system administrator associates each QC test profile with at least one of three definable liquid QC schedules. Each schedule can accommodate up to eight (8) QC test profiles. The liquid QC schedule has an administrator-definable "Due Time" and "Grace Period". The Due Time sets the time when QC Cycles (a test run in the Control pathway consisting of a QC cartridge and a corresponding QC fluid) will begin to count toward completing QC test profiles, i.e. when QC will become "due to start". The Grace Period is the period of time, starting from the Due Time, during which the QC test profile must be completed before the corresponding cartridge set is locked out.

There are a number of options to allow flexibility in the liquid QC schedules. QC Due Times can be set to daily (every day), weekly (on a specified day of the week, e.g. every Tuesday) or monthly (on a specified day of the month e.g. every first Saturday) on selected months and at a defined time of the day. The Grace Period is set in hours, up to 23 hours for daily schedules, up to 167 hours for weekly schedules and up to 255 hours for monthly schedules. The minimum Grace Period is one hour for any schedule type.

C. QC Lockout

By defining a QC test profile with a specified schedule, the system administrator enables the lockout of the corresponding cartridge sets when the QC profile has not been satisfied within the Grace Period. "Lockout" means that the i-STAT 1 Patient and Proficiency pathways are disabled until the QC test profile is satisfied. A QC test profile is satisfied when at least one of each required QC cycle is run and is determined to have "passed". Once a given cartridge set is locked out, its corresponding QC test cycles can still be run on the QC pathway, i.e. the QC pathway is never locked out.

The following important lockout rules apply:

1. Even if multiple Due Times have passed, the QC test profile will only need to be satisfied once to unlock testing (i.e. there is no "build up" of overdue QC cycles).

2. If liquid QC is due for a given schedule, and some of the required QC test profiles are successfully completed but others are not, then when the profile becomes due again, *all* of the QC test profiles within the schedule need to be re-run.

3. If a handheld is configured for information-first with cartridge lot enabled, when the cartridge lot number is scanned in the patient or proficiency pathways, if the cartridge type is locked out, the test cycle will not proceed.

4. **A failed QC cycle in itself will not cause a cartridge set to be locked out.** Lockout occurs only when a QC test profile is past the set grace period and has not been satisfied.

GENERAL NOTES AND CONSIDERATIONS

1. The Liquid QC Schedule and Lockout feature is only available on the i-STAT 1 handheld, and not the i-STAT Portable Clinical Analyzer (i-STAT 200 series model).

2. In order to create Liquid QC Schedules, users must have the i-STAT 1 handheld and either the Central Data Station Version 5 or i-STAT/DE data management applications. This feature is not customizable through the i-STAT 1 handheld keypad.

CAUTION

Use of the Liquid Quality Control Scheduler and Lockout customization features will result in handhelds being unavailable for patient testing when Quality Control requirements are not met.

MINIMUM SOFTWARE REQUIREMENTS

The minimum handheld and data management requirements for use of the Liquid Quality Control Schedule and Lockout customization features are summarized as follows:

System Component	Minimum Software Requirements
i-STAT 1 handheld	≥ JAMS132
Central Data Station Version 5.x	≥ Version 5.26a
i-STAT/DE	≥ Version 2.3

Customizing Liquid QC Schedules on the i-STAT 1 Handheld Using CDS Version 5

1. Click on **Main → Open Administration Function → Customization**

2. Type in your password and click **OK**. The default password is the word *istat*.
    Note: Abbott Point of Care Inc. recommends changing the default password.

3. Make sure the **"Enable Customization"** box has a check mark in it.

    Also, make certain that the **Enable Updates** box is checked for the particular location to which the i-STAT 1 handheld is assigned.

4. If the location where this handheld is assigned has a check mark under **Use Default Profile**, under the **Default customization profile:** column, double click the alphanumeric code under **Preferences.** Otherwise, double click the alphanumeric code under the **Preferences** column for the specific location to which this handheld is assigned.

5. Once the **Preferences** window opens, click on the **Cartridge QC** tab.

6. Click on the **Liquid QC Settings** at the bottom of the screen.

7. In the Control Pass/Fail Determination section, click the radio button for the way in which you will determine the acceptability of liquid QC results:

- None: Disables the QC Pass/Fail and QC Schedule feature.

- Automatic via EVAS: choosing this option indicates that the handheld will automatically determine whether the liquid QC run passed or failed, based upon QC ranges contained on an electronic Value Assignment Sheet (eVAS) file downloaded into the i-STAT 1 handheld. Please see the Technical Bulletin "Liquid Quality Control Pass/Fail Customization on the i-STAT 1 Handheld" for instructions on activating and using this feature.

- Manual: the user will manually compare the liquid QC results to a Value Assignment Sheet downloaded or printed from the Abbott Point of Care (APOC) website at www.abbottpointofcare.com/valsheets and indicate on the handheld whether the QC run passed or failed.

  Note 7.1: The Manual Control Pass/Fail Determination feature is also customizable through the i-STAT 1 handheld keypad.

  1. Power on the i-STAT 1 handheld and press **MENU** to get to the Administration Menu
  2. Press **4 – Customization**
  3. Press **2 – Change**
  4. Type in your password and press **ENT** (If no password is set, just press **ENT**) Note: Abbott Point of Care Inc. recommends changing the default password.
  5. Press **4 – QC Tests**
  6. Press **2 – Cartridge QC**
  7. Press **1** to set Pass / Fail Method

8. If you want users to enter a Comment Code when liquid QC results are in-range, out-of-range, or under both situations, check the appropriate box in the Control Test Settings section and then use the drop down menu to select whether entering the Comment Code is optional (Allow no Comment) or Required (Require Comment).

Note 8.1: Comment Code options can only be selected if one of the Control Pass/Fail Determination methods has been selected (Step 7).

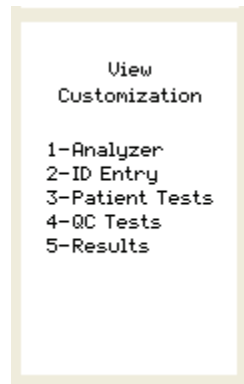**Note 8.2:** The Control Test Settings feature is also customizable through the i-STAT 1 handheld keypad.

1. Power on the i-STAT 1 handheld and press **MENU** to get to the Administration Menu
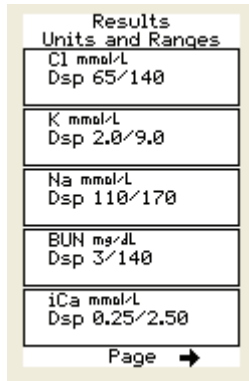2. Press **4 – Customization**
3. Press **2 – Change**
4. Type in your password and press **ENT** (If no password is set, just press **ENT**)
    Note: Abbott Point of Care Inc. recommends changing the default password.
5. Press **4 – QC Tests**
6. Press **2 – Cartridge QC**
7. Press **2** to set Comment Codes for in range results or press **3** to set Comment Codes for out of range results

9. Select the way in which you would like control results to be displayed.

- Numeric: liquid QC results are displayed in numeric format

- Suppressed: the following symbol "< >" is displayed next to each liquid QC test name in place of the quantitative (numeric) results.

    Note 9.1: The "Suppressed" option should only be chosen if "Automatic via EVAS" is chosen for the liquid QC Pass/Fail Determination.

    Note 9.2: The Control Results Display Format is also customizable through the i-STAT 1 handheld keypad.

1. Power on the i-STAT 1 handheld and press **MENU** to get to the Administration Menu
2. Press **4 – Customization**
3. Press **2 – Change**
4. Type in your password and press **ENT** (If no password is set, just press **ENT**)
    Note: Abbott Point of Care Inc. recommends changing the default password.
5. Press **4 – QC Tests**
6. Press **2 – Cartridge QC**
7. Press **4** to set Result Format

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10. Select the method in which control lot number information will be entered into the handheld.

APOC Fluid Lot Entry Method
○ Scan or Enter
○ Scan only

- Scan or Enter: allows the user the option of manually entering the liquid QC lot information into the handheld, or scanning it from the barcode on the quality control vial being tested.

- Scan only: the fluid lot information must be entered by scanning the barcode on the control vial being tested.

Note 10.1: The APOC Fluid Lot Entry Method is also customizable through the i-STAT 1 handheld keypad.

1. Power on the i-STAT 1 handheld and press **MENU** to get to the Administration Menu
2. Press **4 – Customization**
3. Press **2 – Change**
4. Type in your password and press ENT (If no password is set, just press **ENT**)
   Note: Abbott Point of Care Inc. recommends changing the default password.
5. Press **4 – QC Tests**
6. Press **2 – Cartridge QC**
7. Press **5** to set APOC Fluid Lot Method

11. To set up a Liquid QC Schedule, click on the **Liquid QC Schedule 1** tab at the bottom of the screen.
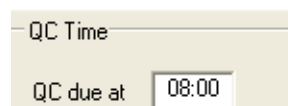
Electronic QC Settings   Liquid QC Settings   Liquid QC Schedule 1

12. Select the frequency at which you want liquid QC to be run under this schedule.

QC Frequency
○ Off   ○ Every Monday
○ Daily   ○ Every first   Monday   of each month

- Off: Disables the selected QC Schedule

- Daily

- Weekly: A particular day of the week (e.g. every Monday)

- Monthly: A particular day of the month (e.g. the second Tuesday of the month).

13. Enter the QC Time. The QC Time sets the time when QC Cycles (a test run in the Control pathway consisting of a QC cartridge and a corresponding QC fluid) will begin to count toward satisfying the QC test profiles, i.e. when QC will become "due to start".

QC Time
QC due at   08:00

Note 13.1: Use the 24 hour clock designation to indicate the time when QC is due. For example, if QC will be due at 2 pm, enter 14:00 for the time.

14. The Grace Period is the period of time, starting from the Due Time, during which the QC test profile must be completed before the corresponding cartridge set is locked out.

Enter the Grace Period in hours:

- up to 23 hours for daily schedules,

- up to 167 hours for weekly schedules, and

- up to 255 hours for monthly schedules.

The minimum Grace Period is one hour for any schedule type.

15. Select the months of the year in which you want this schedule to apply.

- All months

- Selected months. Check the box next to the months to which you want this schedule to apply.

16. To define the Cartridge QC Profile, click **Edit** to the right of the cartridge and fluid lot columns.

The Cartridge Liquid QC Scheduling window will open.

17. Select the QC cartridge type from the drop-down menu. The QC cartridge is the cartridge type to be tested with specified liquid QC fluids during the QC procedure

Note 17.1: Selecting [None] will cease your ability to proceed through the remaining QC Schedule settings.

18. In the Dependent Cartridges section, check the box(es) next to any associated cartridge types that will be enabled by the handheld if the QC requirements for a given cartridge set are met on that handheld.
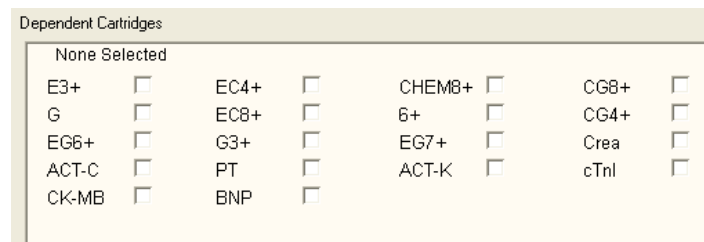
19. In the Cartridge QC Fluids section, select up to six (6) types and levels of control fluid that will be required to be run on the handheld during this QC cartridge schedule timeframe and click **OK**.
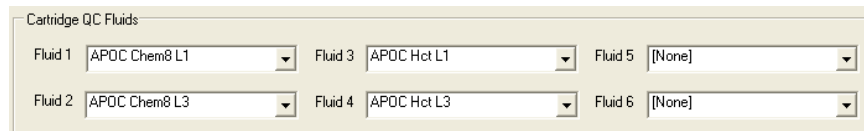
Note 19.1: All i-STAT control fluid types and levels are listed in the drop-down menu, along with three (3) generic user-defined fluids. For a list of the control fluids and their corresponding drop-down menu titles, see the Appendix at the end of this Technical Bulletin.

20. The Cartridge QC profile will then appear on the Liquid QC 1 tab page.

Seven (7) additional Cartridge QC profiles can be created for this Liquid QC Schedule. To create additional Cartridge QC profiles for this schedule, click on **Edit** to the right of the blank Cartridge QC profile and proceed with steps 17-19 above.

21. Once all profiles have been created for a Liquid QC Schedule, additional Liquid QC Schedules can be created by clicking on the next numbered Liquid QC Schedule tab at the bottom of the Cartridge QC tab page. Follow steps 12-20 above to create the additional schedules. Up to three (3) schedules can be created.

22. Once all schedules have been created and defined, click **OK** and answer **YES** to the question about changing the Preferences.
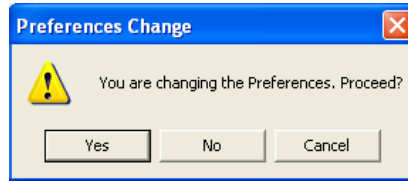
23. Download the handheld(s) to the CDS from a downloader in the location to which the handheld is assigned. This action will upload the chosen customization features into the handheld. Repeat step 23 for all handhelds from the same location to be customized. To customize handhelds from other locations for the same features, return to step 1 of this section.

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Customizing Liquid Quality Schedule and Lockout Features on the i-STAT 1 Handheld Using i-STAT/DE

1. Access the Customization Workspace

   - RALS-Plus Users:

     o Within the RALS-Plus application, pick **i-STAT** from the drop-down menu.

     o Click on **Device Customization**.

   - PrecisionWeb Users::

     o Enter the DE i-STAT Customization Workspace.

2. Make sure the **"Enable Customization"** box has a check mark in it.

   Also, make certain that the **Enabled** box is checked for the particular location to which the i-STAT 1 handheld is assigned.

3. If the location where this handheld is assigned has a check mark under **Uses Default**, under the **Default customization profile:** column, double click the alphanumeric code under **Preferences.** Otherwise, double click the alphanumeric code under the **Preferences** column for the specific location to which this handheld is assigned.

4. Once the **Preferences** window opens, click on the **Cartridge QC** tab.

5. Click on **Liquid QC Settings** at the top of the screen.

6. In the Control Pass/Fail Determination section, click the radio button for the way in which you will determine the acceptability of liquid QC results:
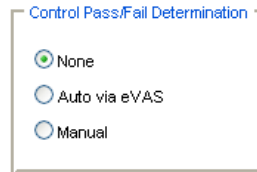
- None: Disables the QC Pass/Fail and QC Schedule feature.

- Auto via eVAS: choosing this option indicates that the handheld will automatically determine whether the liquid QC run passed or failed, based upon QC ranges contained on an electronic Value Assignment Sheet (eVAS) file downloaded into the i-STAT 1 handheld. Please see the Technical Bulletin "Liquid Quality Control Pass/Fail Customization on the i-STAT 1 Handheld" for instructions on activating this feature.

- Manual: the user will manually compare the liquid QC results to a Value Assignment Sheet downloaded or printed from the Abbott Point of Care (APOC) website at www. abbottpointofcare.com/valsheets and indicate on the handheld whether the QC run passed or failed.

   Note 6.1: The Manual Control Pass/Fail Determination feature is also customizable through the i-STAT 1 handheld keypad.

   1. Power on the i-STAT 1 handheld and press **MENU** to get to the Administration Menu
   2. Press **4 – Customization**
   3. Press **2 – Change**
   4. Type in your password and press ENT (If no password is set, just press **ENT**) Note: Abbott Point of Care Inc. recommends changing the default password.
   5. Press **4 – QC Tests**
   6. Press **2 – Cartridge QC**
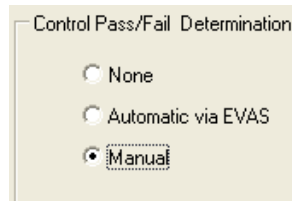   7. Press **1** to set Pass / Fail Method

7. If you want users to enter a Comment Code when liquid QC results are in-range, out-of-range, or under both situations, check the appropriate box(es) in the Control Test Settings section and then use the drop down menu to select whether entering the Comment Code is optional (Allow no Comment) or Required (Require Comment).

   Note 7.1: Comment Code options can only be selected if one of the Control Pass/Fail Determination methods has been selected

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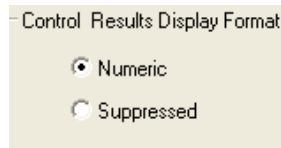**Note 7.2:** The Control Test Settings feature is also customizable through the i-STAT 1 handheld keypad.

1. Power on the i-STAT 1 handheld and press **MENU** to get to the Administration Menu
2. Press **4 – Customization**
3. Press **2 – Change**
4. Type in your password and press **ENT** (If no password is set, just press **ENT**) Note: Abbott Point of Care Inc. recommends changing the default password.
5. Press **4 – QC Tests**
6. Press **2 – Cartridge QC**
7. Press **2** to set Comment Codes for in range results or press **3** to set Comment Codes for out of range results

8. Select the way in which you would like control results to be displayed.

- Numeric: liquid QC results are displayed in numeric format

- Suppressed: the following symbol "< >" is displayed next to each liquid QC test name in place of the quantitative (numeric) results.

  Note 8.1: The "Suppressed" option should only be chosen if "Auto via eVAS" is chosen for the liquid QC Pass/Fail Determination.

  Note 8.2: The Control Results Display Format feature is also customizable through the i-STAT 1 handheld keypad.

  1. Power on the i-STAT 1 handheld and press **MENU** to get to the Administration Menu
  2. Press **4 – Customization**
  3. Press **2 – Change**
  4. Type in your password and press **ENT** (If no password is set, just press **ENT**) Note: Abbott Point of Care Inc. recommends changing the default password.
  5. Press **4 – QC Tests**
  6. Press **2 – Cartridge QC**
  7. Press **4** to set Result Format

9. Select the method in which control lot number information will be entered into the handheld.
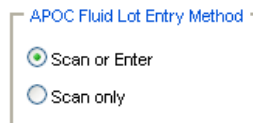
- Scan or Enter: allows the user the option of manually entering the liquid QC lot information into the handheld, or scanning it from the barcode on the quality control vial being tested.

- Scan only: the fluid lot information must be entered by scanning the barcode on the control vial being tested.
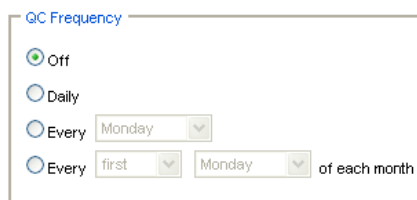
Note 9.1: The APOC Fluid Lot Entry Method is also customizable through the i-STAT 1 handheld keypad.

1. Power on the i-STAT 1 handheld and press **MENU** to get to the Administration Menu
2. Press **4 – Customization**
3. Press **2 – Change**
4. Type in your password and press ENT (If no password is set, just press **ENT**)
   Note: Abbott Point of Care Inc. recommends changing the default password.
5. Press **4 – QC Tests**
6. Press **2 – Cartridge QC**
7. Press **5** to set APOC Fluid Lot Method

10. To set up a Liquid QC Schedule, click on the **Liquid QC Schedule 1** tab at the top of the screen.
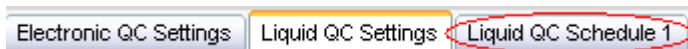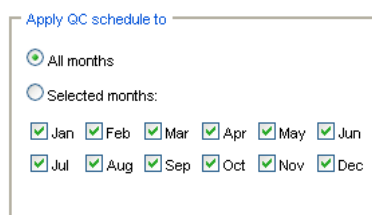
11. Select the frequency at which you want liquid QC to be run under this schedule.
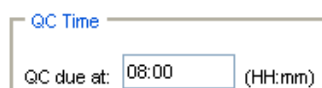
- Off: Disables the selected QC Schedule

- Daily

- A particular day of the week (e.g. every Monday)

- A particular day of the month (e.g. the second Tuesday of the month).

12. Select the months of the year in which you want this schedule to apply.

- All months

- Selected months. Check the box next to the months to which you want this schedule to apply.

13. Enter the QC Time. The QC Time sets the time when QC Cycles (a test run in the Control pathway consisting of a QC cartridge and a corresponding QC fluid) will begin to count toward satisfying the QC test profiles, i.e. when QC will become "due to start".

Note 13.1: Use the 24 hour clock designation to indicate the time when QC is due. For example, if QC will be due at 2 pm, enter 14:00 for the time.

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14. The Grace Period is the period of time, starting from the Due Time, during which the QC test profile must be completed before the corresponding cartridge set is locked out.

    Enter the Grace Period in hours:

    - up to 23 hours for daily schedules,

    - up to 167 hours for weekly schedules, and

    - up to 255 hours for monthly schedules.

    The minimum Grace Period is one hour for any schedule type.

    Grace period: 8   hours

15. To define the Cartridge QC Profile, click **Add a new QC group row…** at the bottom of the screen. The Cartridge QC Profile box will open.

16. Select the QC cartridge type from the drop-down menu. The QC cartridge is the cartridge type to be tested with specified liquid QC fluids during the QC procedure

    Note16.1: Selecting [None] will cease your ability to proceed through the remaining QC Schedule settings.

17. In the Dependent Cartridges section, click **Edit.** Check the box(es) next to any associated cartridge types that will be enabled by the handheld if the QC requirements for a given cartridge set are met on that handheld and then click **Update.**

18. In the Fluids section, select up to six (6) types and levels of control fluid that will be required to be run on the handheld during this QC cartridge schedule timeframe and click **Update.**

Note 18.1: All i-STAT control fluid types and levels are listed in the drop-down menu, along with three (3) generic user-defined fluids. For a list of the control fluids and their corresponding drop-down menu titles, see the Appendix at the end of this Technical Bulletin.

19. The Cartridge QC profile will then appear on the Cartridge QC tab page.

Seven (7) additional Cartridge QC profiles can be created for this Liquid QC Schedule. To create additional Cartridge QC profiles for this schedule, click **Add a new QC Group row…** and proceed with steps 16-18 above.

20. Once all profiles have been created for a Liquid QC Schedule, additional Liquid QC Schedules can be created by clicking on the next numbered Liquid QC Schedule tab at the top of the Cartridge QC tab page. Follow steps 11-19 above to create the additional schedules. Up to three (3) Liquid QC Schedules can be created.

21. Once all schedules have been created and defined, click **OK** and answer **OK** to the question about changing the Preferences.
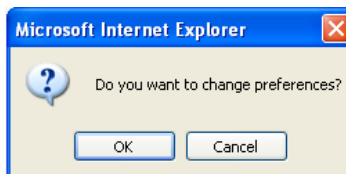
22. Download the handheld(s) to the i-STAT/DE from a downloader in the location to which the handheld is assigned. This action will upload the chosen customization features into the handheld. Repeat step 22 for all handhelds from the same location to be customized. To customize handhelds from other locations for the same features, return to step 1 of this section.

New i-STAT 1 Handheld Display Screens for the Liquid QC Schedule and Lockout Customization Features

After customizing the i-STAT 1 handheld for the new Liquid QC Schedule and Lockout customization features, users may encounter some new handheld display screens.

Test Menu: When the On/Off key is pressed on the handheld, and the Test Menu appears, the handheld will now display one of four messages at the bottom of the screen:

1. "Next i-STAT QC (Date)": This message will appear if users have been compliant in running all liquid QC schedules in this handheld within the customized timeframe. It indicates the upcoming date and time when the grace period begins for the next scheduled liquid QC is due.

```
  06:21 28SEP11

     Test Menu

1-Last Result
2-i-STAT Cartridge



  Next i-STAT QC
  03OCT11 08:00
```
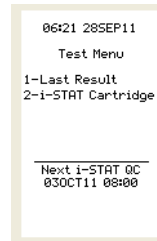
2. "i-STAT QC Due – Complete Before (Date)": This message will appear to remind users that the grace period has begun for one of the liquid QC schedules, and the date and time before which all requirements under that schedule must be completed before analytes are disabled.

```
  10:01 03OCT11

     Test Menu

1-Last Result
2-i-STAT Cartridge



  i-STAT QC Due
 Complete Before
  04OCT11 08:00
```
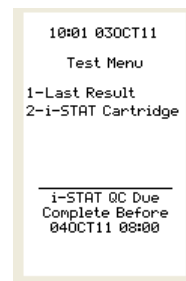
3. "QC Past Due – Not All Cartridges are Active for Testing": This message appears if the liquid QC requirements for a schedule were not completed within the grace period. Some cartridges will be inactive until the schedule requirements are satisfied.

```
  05:57 04OCT11

     Test Menu

1-Last Result
2-i-STAT Cartridge
3-Inactive Carts


 QC Past Due-Not All
   Cartridges Are
  Active For Testing
```
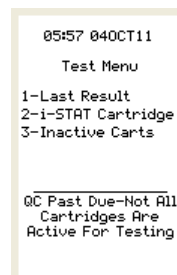
Note 3.1: If this message appears, users can press the listed number on the handheld keypad to display which cartridges are currently inactive.

```
        Inactive Carts

E3+              EC4+
CHEM8+           CG8+
G                6+
G3+              Crea
cTnI
```
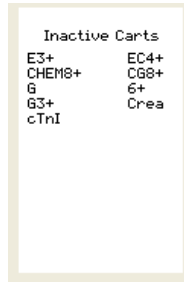
4. "i-STAT QC Past Due – Cartridge Testing Disabled": This message will appear if the liquid QC requirements for a schedule were not completed within the grace period, and if the handheld is configured for "non-information-first" or "information-first with cartridge lot number disabled". In these scenarios, if any cartridge type is locked out, all cartridge types are disabled.

```
     10:48 05OCT11

       Test Menu

  1-Last Result
    -i-STAT Cartridge
  _____
        i-STAT QC
        Past Due
     Cartridge Testing
         Disabled
```
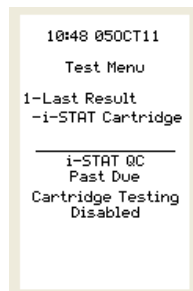
Note: When the handheld is customized for multiple liquid QC schedules, there is a hierarchy which determines which of the four messages above will appear on the Test Menu display. The messages will appear in this order:

i-STAT QC Past Due – Cartridge Testing Disabled
QC Past Due – Not All Cartridges Are Active For Testing
i-STAT QC Due – Complete Before (Date)
Next i-STAT QC (Date)

Quality Tests Menu: When testing liquid QC material and the user has selected 1-Control in the Quality Tests Menu on the handheld, a new "Select QC Event" screen will then appear on the display.

```
     Select QC Event

  1-Unscheduled
  2-Schedule 1
     i-STAT QC Due
     Complete Before
     04OCT11 08:00
```
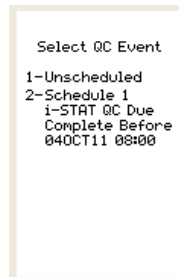
The user has the following options to choose from on this screen:

- 1-Unscheduled: selecting this option allows the user to perform a liquid QC run which will not be applied to a customized liquid QC schedule(s).

- 2-Schedule 1, 3-Schedule 2 (if applicable), or 4-Schedule 3 (if applicable): selecting one of these options will allow the user to apply the liquid QC run to one of the customized schedules.

If the user presses 2, 3 (if applicable), or 4 (if applicable) on this screen, they will then be taken to a screen where they can select the cartridge type to be run.

```
      Select Cartridge

    1-i-STAT CHEM8+ (2)
    2-i-STAT CG8+   (3)
    3-i-STAT cTnI   (2)




         i-STAT QC
         Past Due
```
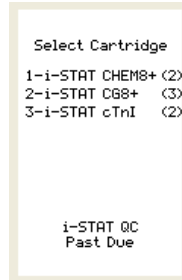
Note: The number in parentheses next to the cartridge name indicates how many control fluids remaining to be run on cartridges of that type and pass in order to satisfy the QC Profile.

Once the cartridge type is selected, the user is taken to a screen to select the fluid type being run.

```
        Select Fluid

    1-APOC CHEM8 L1
    2-APOC CHEM8 L3
    3-APOC HCT L1
    4-APOC HCT L3




         i-STAT QC
         Past Due
```
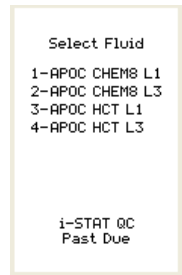
Once the fluid type is selected, the user proceeds as normal.

Manual Pass/Fail Determination: Once the results appear on the screen, if the handheld is customized for Manual Control Pass/Fail Determination, the user will then be prompted to select an outcome as to whether the liquid QC run passed or failed. The user would check the results against the appropriate Value Assignment Sheet, determine if the run passed, or failed, and then press the appropriate key and answer yes to the resulting question in order to store the pass/fail record in the handheld.

```
  Select Outcome        Mark QC PASS?          Control B11004
     1-PASS                 1-Yes             10:21  03OCT11
     2-FAIL                 2-No              i-STAT CHEM8+
                                                   PASS

 Na mmol/L     161     Na mmol/L     161     Na mmol/L     161

 K mmol/L      6.2     K mmol/L      6.2     K mmol/L      6.2

 Cl mmol/L     108     Cl mmol/L     108     Cl mmol/L     108

 iCa mmol/L   0.75     iCa mmol/L   0.75     iCa mmol/L   0.75

 TCO2 mmol/L    35     TCO2 mmol/L    35     TCO2 mmol/L    35


     → Page                 → Page                 → Page
                                               1-Test Options
```
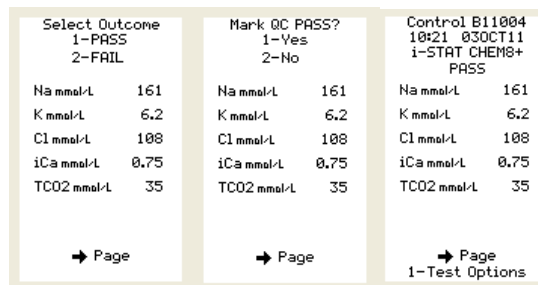
"Automatic via EVAS" Pass/Fail Determination: Examples of handheld display screens when the handheld Control Pass/Fail Determination customization is set to "Automatic via EVAS" can be found in the Technical Bulletin: "Liquid Quality Control Pass/Fail Customization on the i-STAT 1 Handheld".

APPENDIX: LIQUID CONTROL LOT ABBREVIATIONS

The table below lists each i-STAT Control type and corresponding abbreviation used in the Cartridge QC Fluids drop down menus in the Customization Workspace.

Control Name	Control Customization Abbreviation
i-STAT cTnI Control Level 1	APOC cTnI L1
i-STAT cTnI Control Level 2	APOC cTnI L2
i-STAT cTnI Control Level 3	APOC cTnI L3
i-STAT BNP Level 1 Control	APOC BNP L1
i-STAT BNP Level 2 Control	APOC BNP L2
i-STAT BNP Level 3 Control	APOC BNP L3
i-STAT CK-MB Control Level 1	APOC CKMB L1
i-STAT CK-MB Control Level 2	APOC CKMB L2
i-STAT CK-MB Control Level 3	APOC CKMB L3
i-STAT Level 1 Control	APOC i-STAT L1
i-STAT Level 2 Control	APOC i-STAT L2
i-STAT Level 3 Control	APOC i-STAT L3
i-STAT CHEM8+ Level 1 Control	APOC Chem8 L1
i-STAT CHEM8+ Level 2 Control	APOC Chem8 L2
i-STAT CHEM8+ Level 3 Control	APOC Chem8 L3
RNA Medical Hematocrit Level 1 Control	APOC Hct L1
RNA Medical Hematocrit Level 2 Control	APOC Hct L2
RNA Medical Hematocrit Level 3 Control	APOC Hct L3
i-STAT ACT Level 1 Control	APOC ACT L1
i-STAT ACT Level 2 Control	APOC ACT L2
i-STAT PT Level 1 Control	APOC PT L1
i-STAT PT Level 2 Control	APOC PT L2
Level 1 Control – Non-i-STAT	Non-APOC L1
Level 2 Control – Non-i-STAT	Non-APOC L2
Level 3 Control – Non-i-STAT	Non-APOC L3
i-STAT TriControls Level 1	APOC Combo L1
i-STAT TriControls Level 2	APOC Combo L2
i-STAT TriControls Level 3	APOC Combo L3

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i-STAT®
TECHNICAL BULLETIN

LIQUID QUALITY CONTROL PASS/FAIL CUSTOMIZATION ON THE i-STAT 1 HANDHELD

OVERVIEW

As part of the on-going READi initiative (**R**esponds, **E**nhances, **A**nd **D**elivers **I**nnovations), Abbott Point of Care (APOC) has released a new Liquid Quality Control Automatic Pass/Fail (QC Auto P/F) customization feature for the i-STAT 1 handheld. This feature can automatically determine if the results of a liquid QC test run on an i-STAT cartridge are within APOC's published quality control ranges. Since control ranges vary with the handheld's CLEW software version and with   i-STAT cartridge and control lot numbers, manually applying the correct control limits can be cumbersome; with QC Auto P/F, the potential for this human error is avoided. Used in conjunction with the new Liquid QC Schedule and Lockout customization features, QC Auto P/F helps a system administrator (e.g. Point of Care Coordinator or Laboratory Administrator) assure compliance with QC requirements. By default, the feature is turned off.

For more information on the Liquid QC Schedule and Lockout customization features, please see the Technical Bulletin: "Liquid Quality Control Schedule and Lockout Customization on the i-STAT 1 Handheld".

Functionality

Previously, i-STAT 1 users performing liquid quality control tests on i-STAT cartridges had to manually determine the acceptability of the results by accessing Value Assignment Sheets (VAS) posted on the APOC website and comparing each test result value to the corresponding listed control range.

With the new QC Auto P/F feature, the system administrator can go to the APOC website and download an electronic value assignment sheet (eVAS) file: an electronic file containing the complete set of the data from the current i-STAT QC Value Assignment Sheets. By saving the eVAS file to a specified directory, the eVAS is available to the i-STAT Central Data Station (CDS) or i-STAT/DE software applications. Once the file is downloaded and the eVAS feature is enabled in the Customization Workspace, the file is transferred to individual i-STAT 1 handhelds the next time they download data to the CDS or i-STAT/DE applications. Each i-STAT 1 handheld will then have a complete database of all current i-STAT control ranges stored in its memory.

When testing liquid QC samples with i-STAT cartridges on an i-STAT 1 handheld customized for the new QC Auto P/F feature, the user scans barcodes from both the control fluid vial and the cartridge pouch. Using this information, the handheld automatically evaluates each measured test result for acceptability against the control ranges defined in the eVAS. A "Pass" or "Fail" status is determined for each result, and an overall determination of "Pass" is made if every measured analyte in the test panel passes. The status of individual failed results will be displayed on the handheld as either an up-arrow (↑) for out-of-range high results, or a down-arrow (↓) for out-of-range low results. The overall determination for the QC test panel is indicated by a PASS or FAIL message being displayed above the results.

Abbott
Point of Care

GENERAL NOTES AND CONSIDERATIONS

1. The QC Auto P/F customization feature is only available on the i-STAT 1 handheld, and not the i-STAT Portable Clinical Analyzer (i-STAT 200 series model).

2. In order to use the QC Auto P/F customization feature, users must have the i-STAT 1 handheld and either the Central Data Station Version 5 or i-STAT/DE data management applications.

3. The QC Auto P/F customization feature is designed to work in the i-STAT 1 handheld control testing pathway with all liquid QC products that are assigned control ranges in APOC's Value Assignment Sheets (available on the APOC website: www.abbottpointofcare.com/valsheets). QC Auto P/F is not available for third-party control materials or for APOC Calibration Verification product.

4. With each liquid QC run, the following information is transmitted when results are downloaded to the CDS or i-STAT/DE:

   - The QC results,

   - The eVAS file name,

   - The i-STAT cartridge and control fluid lot numbers, and

   - The overall Pass/Fail result determined for the liquid QC test run.

5. Unless numerical results have been suppressed through customization, when the results of a liquid QC run are printed, each analyte value is displayed on the printout, along with the corresponding control range. The symbol "<< >>" is used to indicate out-of-range results on the printout.

6. When the i-STAT 1 handheld is customized for QC Auto P/F, non-APOC controls may be tested in the control pathway, but the Pass/Fail assignment must be performed manually.

CAUTIONS

1. When testing liquid controls, if the handheld is customized for User Defined Reportable Ranges and Auto Pass/Fail detection, the handheld will display the control result based upon the customized Reportable Range setting, but will base the Auto Pass/Fail determination on the measured analyte value, irrespective of the Reportable Range settings.

2. Use caution to protect against cuts if scanning a barcode from an open glass control ampule.

MINIMUM SOFTWARE REQUIREMENTS

The minimum handheld and data management software requirements for use of the QC Auto P/F customization feature are summarized as follows:

System Component	Minimum Software Requirements
i-STAT 1 handheld	$\geq$ JAMS132
Central Data Station Version 5.x	$\geq$ Version 5.26a
i-STAT/DE	$\geq$ Version 2.3

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DOWNLOADING AN ELECTRONIC VALUE ASSIGNMENT SHEET (eVAS) FROM THE APOC WEBSITE FOR USE WITH THE CDS OR i-STAT/DE CUSTOMIZATION WORKSPACES

1. Navigate to the eVAS page of the APOC website: www.abbottpointofcare.com/eVas.

2. Choose the CLEW from the dropdown menu. Click the **Save** button that appears.

3. When a File Download box opens, Click **Save.** A Save As box will then open.

4. When the **Save As** box opens, select the destination folder where the eVAS file will be saved and click **Save**.

   Note: 4.1 <u>DO NOT rename the file</u>. The Customization Workspace in CDS and i-STAT/DE will not recognize the eVAS file if it has been renamed.

   - CDS Users: If using the same computer where CDS resides, select **C:\Istat32\VAS** as the file destination otherwise save the file to any directory and transfer to the CDS location.

   - i-STAT/DE Users: choose any directory on a network which is accessible to i-STAT/DE. However, remember to note the destination directory, as it will need to be accessed later when activating the eVAS, illustrated in section "Customizing the i-STAT 1 Handheld For Liquid QC Auto P/F Using i-STAT/DE", and Auto QC P/F features. NOTE: It is recommended that older eVAS files be archived in a separate directory or deleted after being uploaded to i-STAT DE.

5. When the Download Complete Box opens, click **Close**. The web browser window may now be closed.

CUSTOMIZING THE i-STAT 1 HANDHELD FOR LIQUID QC P/F USING CDS VERSION 5

1. Click on **Main** → **Open Administration Function** → **Customization.**

2. Type in your password and click **OK**. The default password is the word *istat*.
   Note: Abbott Point of Care Inc. recommends changing the default password.

3. Make sure the **"Enable Customization"** box has a check mark in it.

Also, make certain that the **Enable Updates** box is checked for the particular location to which the i-STAT 1 handheld is assigned.

4. At the bottom of the **Default customization profile:** column, check the **Use eVAS** box.

5. If the location where this handheld is assigned has a check mark under **Use Default Profile**, under the **Default customization profile:** column, double click the alphanumeric code under **Preferences.** Otherwise, double click the alphanumeric code under the **Preferences** column for the specific location to which this handheld is assigned.

6. Once the **Preferences** window opens, click on the **Cartridge QC** tab.

7. Click on the **Liquid QC Settings** at the bottom of the screen.

8. In the Control Pass/Fail Determination section, click the **Automatic via EVAS** radio button. Choosing this option indicates that the handheld will automatically determine whether the liquid QC run passed or failed, based upon QC ranges contained on an electronic Value Assignment Sheet (eVAS) file downloaded into the i-STAT 1 handheld.
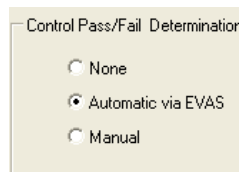
Note 8.1: The Manual Control Pass/Fail Determination feature is also customizable through the i-STAT 1 handheld keypad.

1. Power on the i-STAT 1 handheld and press **MENU** to get to the Administration Menu
2. Press **4 – Customization**
3. Press **2 – Change**
4. Type in your password and press **ENT** (If no password is set, just press **ENT**)
   Note: Abbott Point of Care Inc. recommends changing the default password.
5. Press **4 – QC Tests**
6. Press **2 – Cartridge QC**
7. Press **1** to set Pass / Fail Method
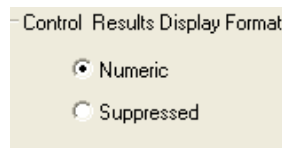
9. If you want users to enter a Comment Code when liquid QC results are in-range, out-of-range, or under both situations, check the appropriate box in the Control Test Settings section and then use the drop down menu to select whether entering the Comment Code is optional (Allow no Comment) or Required (Require Comment).

Note 9.1: The Control Test Settings feature is also customizable through the i-STAT 1 handheld keypad.

1. Power on the i-STAT 1 handheld and press **MENU** to get to the Administration Menu
2. Press **4 – Customization**
3. Press **2 – Change**
4. Type in your password and press **ENT** (If no password is set, just press **ENT**)
   Note: Abbott Point of Care Inc. recommends changing the default password.
5. Press **4 – QC Tests**
6. Press **2 – Cartridge QC**
7. Press **2** to set Comment Codes for in range results or press **3** to set Comment Codes for out of range results

10. Select the way in which you would like control results to be displayed.

- Numeric: liquid QC results are displayed in numeric format.

- Suppressed: the following symbol "< >" is displayed next to each liquid QC test name in place of the quantitative (numeric) results.

Note 10.1: The "Suppressed" option should only be chosen if "Automatic via EVAS" is chosen for the liquid QC Pass/Fail Determination.

Note 10.2: The Control Results Display Format is also customizable through the i-STAT 1 handheld keypad.

1. Power on the i-STAT 1 handheld and press **MENU** to get to the Administration Menu
2. Press **4 – Customization**
3. Press **2 – Change**
4. Type in your password and press **ENT** (If no password is set, just press **ENT**)
   Note: Abbott Point of Care Inc. recommends changing the default password.
5. Press **4 – QC Tests**
6. Press **2 – Cartridge QC**
7. Press **4** to set Result Format

11. Select the method in which control lot number information will be entered into the handheld.
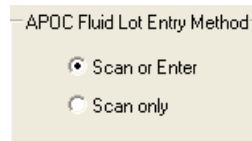
- Scan or Enter: allows the user the option of manually entering the liquid QC lot information into the handheld or scanning it from the barcode on the quality control vial being tested.

- Scan only: the fluid lot information must be entered by scanning the bar code on the control vial being tested.

Note 11.1: If customizing handhelds for Auto QC P/F, users must scan the barcode on the APOC control vial when testing APOC liquid QC samples. If testing non-APOC controls, users may scan the barcode from the control vial or enter the control lot number manually.

Note 11.2: The APOC Fluid Lot Entry Method is also customizable through the i-STAT 1 handheld keypad.

1. Power on the i-STAT 1 handheld and press **MENU** to get to the Administration Menu
2. Press **4 – Customization**
3. Press **2 – Change**
4. Type in your password and press **ENT** (If no password is set, just press **ENT**)
   Note: Abbott Point of Care Inc. recommends changing the default password.
5. Press **4 – QC Tests**
6. Press **2 – Cartridge QC**
7. Press **5** to set APOC Fluid Lot Method

12. Click **OK** and answer **YES** to the question about changing the Preferences.
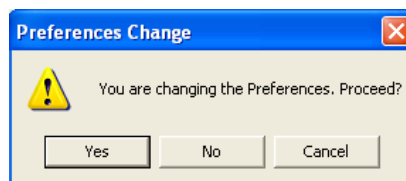
13. Download the handheld(s) to the CDS from a downloader in the location to which the handheld is assigned. This action will upload the chosen customization features into the handheld. Repeat step 13 for all handhelds from the same location to be customized. To customize handhelds from other locations for the same features, return to step 1 of this section.

CUSTOMIZING THE i-STAT 1 HANDHELD FOR LIQUID QC P/F USING i-STAT/DE

1. Access the Customization Workspace.

    - RALS-Plus Users:

        o Within the RALS-Plus application, pick **i-STAT** from the drop-down menu.

        o Click on **Device Customization**.

    - PrecisionWeb Users:

        o Enter the DE i-STAT Customization Workspace.

2. Make sure the **"Enable Customization"** box has a check mark in it.
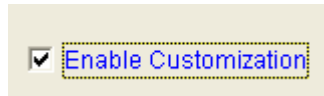
    Also, make certain that the **Enabled** box is checked for the particular location to which the i-STAT 1 handheld is assigned.

3. To upload the eVAS file to i-STAT/DE, at the top of the Customization Workspace, click **Update i-STAT/DE** and select **Upload Update File.**

4. When the **"Specify file for i-STAT/DE update:" box opens,** Click **Browse…**
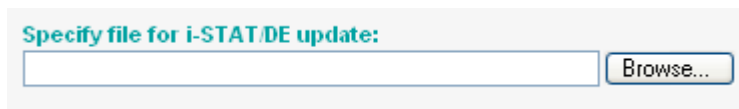
5. Navigate to the directory location of where the eVAS file was saved. Select the eVAS file and Click **Open.**
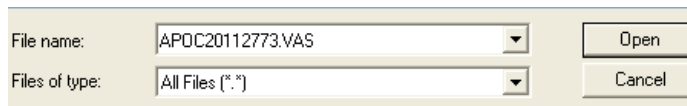
6. Click **Upload**. If successful, a confirmation will appear that the file has been uploaded.

7. Click **Cancel**. The application will return to the Customization Workspace.

8. At the bottom of the **Default customization profile:** column, check the **Use eVAS** box.

9. If the location where this handheld is assigned has a check mark under **Uses Default**, under the **Default customization profile:** column, double click the alphanumeric code under **Preferences.** Otherwise, double click the alphanumeric code under the **Preferences** column for the specific location to which this handheld is assigned.

10. Once the Preferences window opens, click on the Cartridge QC tab.

11. Click on **Liquid QC Settings** at the top of the screen.

12. In the Control Pass/Fail Determination section, click the **Auto via eVAS** radio button. Choosing this option indicates that the handheld will automatically determine whether the liquid QC run passed or failed, based upon QC ranges contained on an electronic Value Assignment Sheet (eVAS) file downloaded into the i-STAT 1 handheld.

Note 12.1: The Manual Control Pass/Fail Determination feature is also customizable through the i-STAT 1 handheld keypad.

1. Power on the i-STAT 1 handheld and press **MENU** to get to the Administration Menu
2. Press **4 – Customization**
3. Press **2 – Change**
4. Type in your password and press **ENT** (If no password is set, just press **ENT**)
   Note: Abbott Point of Care Inc. recommends changing the default password.
5. Press **4 – QC Tests**
6. Press **2 – Cartridge QC**
7. Press **1** to set Pass / Fail Method
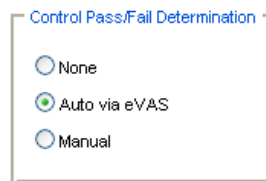
13. If you want users to enter a Comment Code when liquid QC results are in-range, out-of-range, or under both situations, check the appropriate box(es) in the Control Test Settings section and then use the drop down menu to select whether entering the Comment Code is optional (Allow no Comment) or Required (Require Comment).
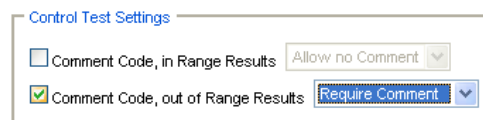
Note 13.1: The Control Test Settings feature is also customizable through the i-STAT 1 handheld keypad.

1. Power on the i-STAT 1 handheld and press **MENU** to get to the Administration Menu
2. Press **4 – Customization**
3. Press **2 – Change**
4. Type in your password and press **ENT** (If no password is set, just press **ENT**)
   Note: Abbott Point of Care Inc. recommends changing the default password.
5. Press **4 – QC Tests**
6. Press **2 – Cartridge QC**
7. Press **2** to set Comment Codes for in range results or press **3** to set Comment Codes for out of range results

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14. Select the way in which you would like control results to be displayed.

Control Results Display Format
- ⦿ Numeric
- ○ Suppressed

- Numeric: liquid QC results are displayed in numeric format.

- Suppressed: the following symbol "< >" is displayed next to each liquid QC test name in place of the quantitative (numeric) results.

Note 14.1: The "Suppressed" option should only be chosen if "Automatic via EVAS" is chosen for the liquid QC Pass/Fail Determination.

Note 14.2: The Control Results Display Format is also customizable through the i-STAT 1 handheld keypad.

1. Power on the i-STAT 1 handheld and press **MENU** to get to the Administration Menu
2. Press **4 – Customization**
3. Press **2 – Change**
4. Type in your password and press **ENT** (If no password is set, just press **ENT**)
   Note: Abbott Point of Care Inc. recommends changing the default password.
5. Press **4 – QC Tests**
6. Press **2 – Cartridge QC**
7. Press **4** to set Result Format

15. Select the method in which control lot number information will be entered into the handheld.

APOC Fluid Lot Entry Method
- ⦿ Scan or Enter
- ○ Scan only
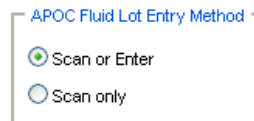
- Scan or Enter: allows the user the option of manually entering the liquid QC lot information into the handheld or scanning it from the barcode on the quality control vial being tested.

- Scan only: the fluid lot information must be entered by scanning the barcode on the control vial being tested.

Note 15.1: If customizing handhelds for Auto QC P/F, users <u>must</u> scan the barcode on the APOC control vial when testing APOC liquid QC samples. If testing non-APOC controls, users may scan the barcode from the control vial <u>or</u> enter the control lot number manually.

Note 15.2: The APOC Fluid Lot Entry Method is also customizable through the i-STAT 1 handheld keypad.

1. Power on the i-STAT 1 handheld and press **MENU** to get to the Administration Menu
2. Press **4 – Customization**
3. Press **2 – Change**
4. Type in your password and press **ENT** (If no password is set, just press **ENT**)
   Note: Abbott Point of Care Inc. recommends changing the default password.
5. Press **4 – QC Tests**
6. Press **2 – Cartridge QC**
7. Press **5** to set APOC Fluid Lot Method

16. Click **OK** and answer **OK** to the question about changing the Preferences.
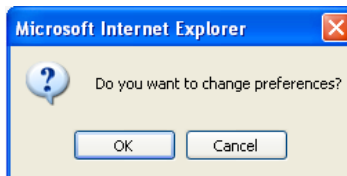
17. Download the handheld(s) to the i-STAT/DE from a downloader in the location to which the handheld is assigned. This action will upload the chosen customization features into the handheld. Repeat step 17 for all handhelds from the same location to be customized. To customize handhelds from other locations for the same features, return to step 1 of this section.

CONFIRMING THAT THE eVAS HAS BEEN TRANSFERRED TO THE i-STAT 1 HANDHELD FROM CDS VERSION 5 or i-STAT/DE

1. Power on the i-STAT 1 handheld and press **MENU** once to get to the Administration Menu.

2. Press **4 -Customization.**

```
14:36 26JUL11

Administration Menu

1-Analyzer Status
2-Data Review
3-Quality Tests
4-Customization
5-Set Clock
6-Transmit Data
7-Utility
```

3. Press **1-View.**

```
Customization
    11726BP9

    1-View
    2-Change
```

4. Press **4-QC Tests**.

```
      View
  Customization

  1-Analyzer
  2-ID Entry
  3-Patient Tests
  4-QC Tests
  5-Results
```

5. Press **2-Cartridge QC**.
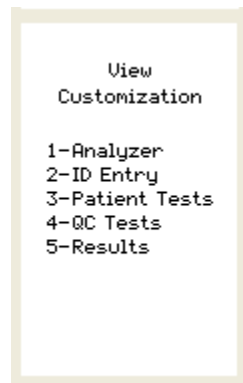
```
         View
     Customization
       QC Tests

     1-Simulator
     2-Cartridge QC
```
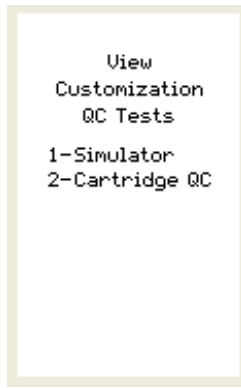
6. Press the → key to view the eVAS Name that has been transferred to the handheld.

```
     Cartridge QC
     Customization
   eVAS Name
   APOC20112773.VAS




    ←    Page
```

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NEW i-STAT 1 HANDHELD DISPLAY SCREENS FOR THE LIQUID QC PASS/FAIL CUSTOMIZATION FEATURE

After customizing the i-STAT 1 handheld for the new Liquid QC Auto P/F customization feature, users may encounter some new handheld display screens.

Quality Tests Menu: If the QC Auto P/F customization feature is being used in conjunction with the Liquid QC Schedule customization feature, and the user has selected 1-Control in the Quality Tests Menu on the handheld, a new "Select QC Event" screen will appear on the display.

```
Select QC Event

1-Unscheduled
2-Schedule 1
  i-STAT QC
  Past Due
```
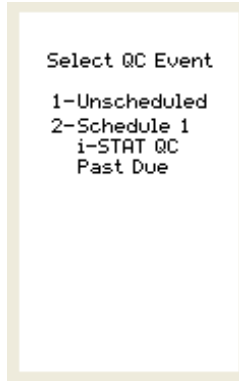
If the user selects 1-Unscheduled, and then enters/scans their operator ID, the handheld will display a new screen requesting that they select a Fluid Vendor.

```
   Select
 Fluid Vendor

1-APOC
2-Non-APOC
```
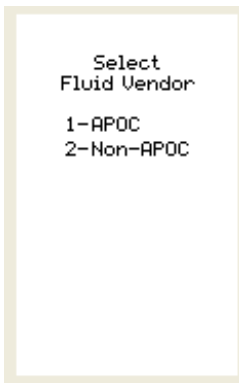
Once a Fluid Vendor is selected, the user will then be asked to select a Fluid Level.

```
Select Fluid

1-Level 1
2-Level 2
3-Level 3
```
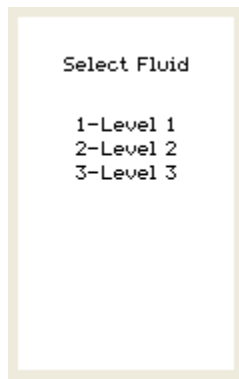
If a Non-APOC fluid has been selected, the user will then be asked to Scan or Enter the Control Lot Number. If an APOC fluid has been selected, the user will then be asked to scan the Control Lot Number.

```
┌──────────────────┐      ┌──────────────────┐
│  Scan or Enter   │      │      Scan        │
│     Control      │      │    Control       │
│   Lot Number     │      │   Lot Number     │
│                  │      │                  │
│                  │      │                  │
│    -------       │      │    -------       │
│                  │      │                  │
│                  │      │                  │
│                  │      │                  │
│                  │      │                  │
└──────────────────┘  OR  └──────────────────┘
```
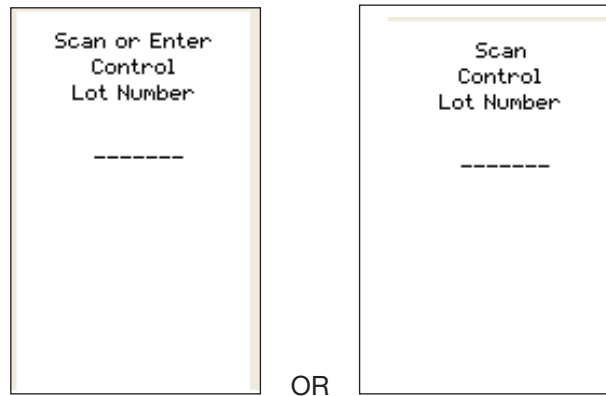
Liquid QC Results Screens: If the i-STAT 1 handheld is customized for the QC Auto P/F feature, the Liquid QC results screen appearance will vary, depending on whether the handheld is customized to display control results in a Numeric format, or whether they are Suppressed, along with whether the QC run Passed or Failed.

- • Numeric Control Result Display with a Passed QC run:

```
┌──────────────────┐
│  Control 151024  │
│   10:40  14OCT11 │
│   i-STAT CHEM8+  │
│       PASS       │
│                  │
│ Na mmol/L    120 │
│                  │
│ K mmol/L     2.8 │
│                  │
│ Cl mmol/L     77 │
│                  │
│ iCa mmol/L  1.46 │
│                  │
│ TCO2 mmol/L   17 │
│                  │
│                  │
│        ➡ Page    │
│   1-Test Options │
└──────────────────┘
```
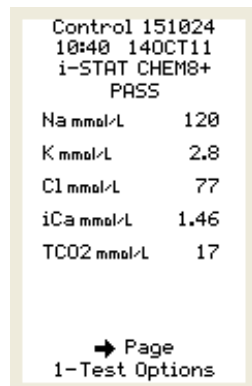
- • Numeric Control Result Display with a Failed QC run: The status of individual failed results is displayed on the handheld as either an up-arrow (↑) for out-of-range high results, or a down-arrow (↓) for out-of-range low results.

```
┌──────────────────┐
│  Control 151024  │
│   10:51  14OCT11 │
│   i-STAT CHEM8+  │
│       FAIL       │
│                  │
│ Na mmol/L   135▲ │
│                  │
│ K mmol/L    3.7▲ │
│                  │
│ Cl mmol/L    90▲ │
│                  │
│ iCa mmol/L 1.25▼ │
│                  │
│ TCO2 mmol/L   23 │
│                  │
│                  │
│        ➡ Page    │
│   1-Test Options │
└──────────────────┘
```
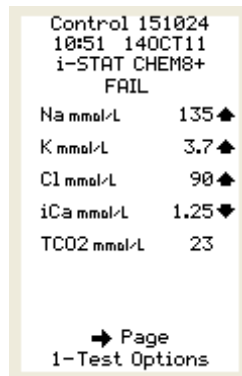
- Suppressed Control Result Display with a Passed QC run: All analyte results will display a <> symbol and the overall Pass assessment appears at the top of the display screen above the results.

```
Control 151024
 10:58  14OCT11
 i-STAT CHEM8+
      PASS
Na mmol/L        <>
K mmol/L         <>
Cl mmol/L        <>
iCa mmol/L       <>
TCO2 mmol/L      <>


       → Page
 1-Test Options
```
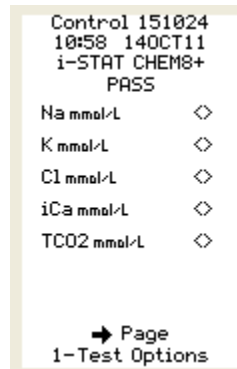
- Suppressed Control Result Display with a Failed QC run: All analyte results will display a <> symbol and the overall Fail assessment appears at the top of the display screen above the results. The status of individual failed results is displayed on the handheld as either an up-arrow (↑) for out-of-range high results, or a down-arrow (↓) for out-of-range low results.

```
Control 151024
 11:06  14OCT11
 i-STAT CHEM8+
      FAIL
Na mmol/L        <> ▲
K mmol/L         <> ▲
Cl mmol/L        <> ▲
iCa mmol/L       <> ▼
TCO2 mmol/L      <>


       → Page
 1-Test Options
```
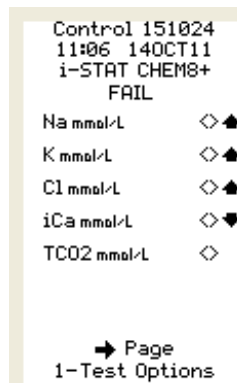
HANDHELD DISPLAY MESSAGES

The following messages may appear on the i-STAT 1 handheld when it is customized for Auto QC P/F:

Message	Cause
Invalid eVAS	The eVAS file does not exist or is invalid. Download current eVAS file from the APOC website Value Assignment Sheet page.
Lot Not in eVAS	The entered cartridge or control lot number could not be found in eVAS file. Download current eVas file from the APOC website Value Assignment Sheet page.
Does Not Match Selected Level	The entered control solution lot number does not match the user selected control level.
Invalid Length	A blank control solution lot number was entered.
Lot Expired	The entered control solution lot number or Cartridge lot number is expired.
Invalid Number	The scanned APOC lot number has an invalid format.

Art: 730078-00C

i-STAT®
TECHNICAL BULLETIN

POSITIVE PATIENT IDENTIFICATION (PPID) CUSTOMIZATION ON THE i-STAT 1 HANDHELD

OVERVIEW

As part of the on-going READi initiative (**R**esponds, **E**nhances, **A**nd **D**elivers **I**nnovation), Abbott Point of Care (APOC) has released a new Positive Patient Identification (PPID) feature for the i-STAT 1 handheld. This feature enables the handheld to present secondary patient identifiers (patient's name, birth date, and gender) obtained from the hospital's Admission, Discharge, and Transfer (ADT) data based upon the entered patient identification number. Using these secondary identifiers, the identity of the patient can be confirmed by the handheld operator.

The PPID feature helps hospitals comply with The Joint Commission National Patient Safety Goal of improving the accuracy of patient identification by obtaining at least two forms of patient identification prior to diagnostic testing.

GENERAL NOTES AND CONSIDERATIONS

1. The PPID feature is available only through the i-STAT 1 handheld, and requires the use of the RAL-Plus or PrecisionWeb data managers with i-STAT/DE. The PPID feature cannot be utilized with the Central Data Station application. It cannot be enabled or disabled through keypad customization. The feature is not supported by the i-STAT Portable Clinical Analyzer.

2. By default, the PPID feature is turned off.

3. Implementation of PPID requires an interface to the facility's ADT feed be implemented in the data management software. **Contact your data management vendor for information on having this interface implemented.**

4. Other patient ID entry customization options available previously (e.g. repeat ID entry or minimum / maximum ID length) have not changed with the addition of PPID.

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CAUTIONS

1. If the lockout override is disabled, a patient test cannot be run unless the entered patient ID is in the handheld's internal patient list.

2. In order to ensure that the patient list stored in the handheld is current, the i-STAT 1 handhelds must be downloaded regularly in order to obtain patient list updates.

MINIMUM SOFTWARE REQUIREMENTS

The minimum handheld and data management requirements for use of the PPID customization feature are summarized as follows:

System Component	Minimum Software Requirements
i-STAT 1 handheld	≥ JAMS132
i-STAT/DE	≥ Version 2.3
RALS Plus	≥ Version 2.7
PrecisionWeb	≥ SP5

FUNCTIONALITY

With the new PPID feature enabled, each time an i-STAT 1 handheld is downloaded, the facility-wide list of valid patient ID numbers and associated secondary identifiers stored in the handheld is updated. During subsequent cartridge testing, when the operator scans a bar-coded wrist band or manually enters a patient ID number, the handheld verifies the entered patient ID is found in the handheld's patient list. If the patient ID is found in the handheld's patient list, the handheld will display the patient's name, birth date, and gender on the screen. The operator can then verify that these identifiers match the patient being tested. Optionally, display of the birth date can be suppressed, and the operator will have to enter the birth date correctly to confirm the patient ID. After successful patient ID confirmation, the cartridge testing process would proceed as usual.

IMPLEMENTATION

A.   Patient List Requirements

The i-STAT 1 PPID feature maintains one active patient list per facility, ensuring patients are recognized wherever they are located in the facility.

This active patient list is obtained from the facility ADT database by the data manager (RALS Plus or PrecisionWeb). **The maximum number of active patients permitted on the i-STAT 1 patient list is 6000 per facility.**

B.   Identifier Formats

The format for the primary and secondary identifiers displayed on the handheld screen is as follows:

Primary Identifier	Format
Patient ID (e.g. Medical Record Number or Account Number)	Up to 15 characters
Secondary Identifier	**Format**
Last Name	Up to 15 characters
First Initial	Single Character
Middle Initial	Single Character
Date of Birth (DOB)	DDMMMYYYY
Gender: Male, Female, Other, Unknown	Single Character (M, F, O, U)

Note 1: If desired, the secondary identifiers can be configured to print with test results on the i-STAT or Martel printers. Default behavior is to not print the secondary identifiers.
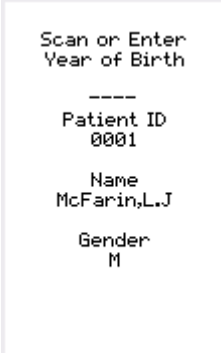
Note 2: When patient test results are transmitted to the data manager, the secondary identifiers along with a status flag indicating whether the patient ID was confirmed are included in the transmitted test record.

C.   PPID Customization Options
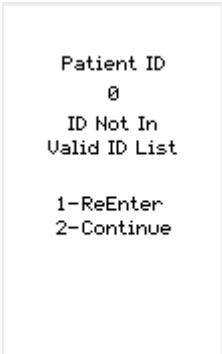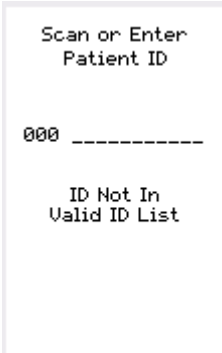
There are a number of customization options available to tailor the handheld's PPID behavior to meet the specific needs of the facility. Customization options are selected from the Customization Workspace in i-STAT/DE.

1. **Confirmation Method:** The system administrator (e.g. Point of Care Coordinator or Laboratory Administrator) can select among 3 methods for operators to confirm the patient identity. The choices are:

Confirmation Method	Operator Action	Handheld Display Example
Confirm (Default setting)	The operator confirms the patient ID by selecting "Continue".	Patient ID 0001 / Name McFarin,L.J / Date of Birth 08APR1997 / Gender M / 1-ReEnter 2-Continue
Replicate Year of Birth	The operator enters the four digits of the patient's year of birth to confirm the patient ID. The date of birth **is** displayed on the handheld screen.	Scan or Enter Year of Birth ---- Patient ID 0001 / Name McFarin,L.J / Date of Birth 08APR1997 / Gender M

Enter Year of Birth	The operator enters the four digits of the patient's year of birth to confirm the patient ID. The date of birth **is not** displayed on the handheld screen.	Scan or Enter Year of Birth ---- Patient ID 0001 Name McFarin,L.J Gender M

2. Not On List Action: The system administrator can select the desired behavior when the entered patient ID is not found in the handheld's patient list. The choices are:

Action, Not on List	Action Definition	Handheld Display Example
Disabled (Default setting)	The PPID is not active. No warning or lockout is displayed on the handheld.	N/A
Warn	The operator is warned that the patient ID is not found in the active patient list.	Patient ID 0 ID Not In Valid ID List 1-ReEnter 2-Continue
Lockout	Testing cannot be performed using this Patient ID.	Scan or Enter Patient ID 000 _____ ID Not In Valid ID List

Note 2.1: If Lockout is chosen above, the system administrator can choose to enable or disable a lockout override. If the override is enabled, the operator can override the lockout by selecting option 2 to continue.

Note 2.2: If Year of Birth is required for confirmation, but no Year of Birth is available in the patient list, the patient ID will be considered not on the list.

3. Print ID Attributes: The system administrator can select whether secondary patient identifiers (Name, DOB, Gender) print with test results on the i-STAT or Martel printers.
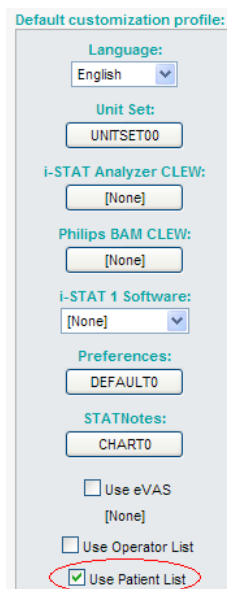
1. Access the Customization Workspace

    - RALS-Plus Users:

        o Within the RALS-Plus application, pick **i-STAT** from the drop-down menu.

        o Click on **Device Customization**.

    - PrecisionWeb Users::

        o Double-click the Desktop shortcut for the i-STAT Customization Workspace

2. Ensure **Enable Customization is** checked.

    Also, ensure **Enabled** is checked for the particular location to which the i-STAT 1 handheld is assigned.

3. At the bottom of the **Default Customization profile:** area, check **Use Patient List**.

4. If the location where this handheld is assigned has a check in the **Uses Default column**, click the button displaying the alphanumeric code under **Preferences** in the **Default customization profile:** area**.** Otherwise, click the button displaying the alphanumeric code in the **Preferences** column for the specific location to which this handheld is assigned.
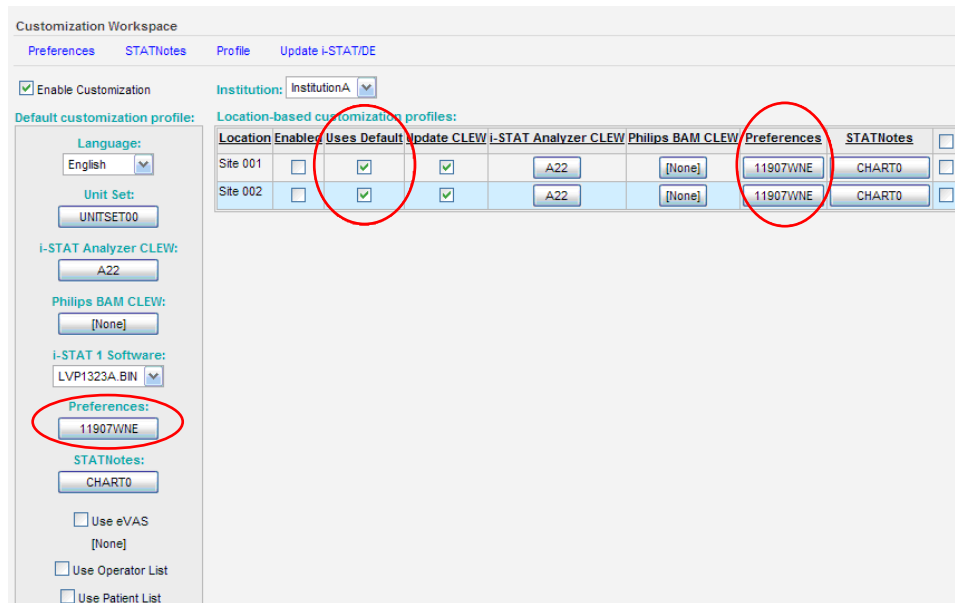
5. Once the **Preferences** page is displayed, click on the **ID Entry** tab.

6. In the Positive Patient ID section at the bottom of the page, check **Action Not on List** and select the desired behavior when the entered patient ID is not found in the handheld's patient list:
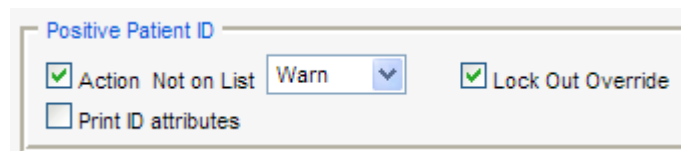
- Warn: The operator is warned that the patient ID is not found in the active patient list.

- Lock Out: The operator is locked out from patient testing using the given patient ID.

Note 6.1: If you do not want the handheld to take any action if the entered patient ID is not found on the handheld's patient list, leave the **Action Not on List** option unchecked.

7. If Lock Out is chosen in step 6 above, check **Lock Out Override** if you want operators to be able to override the lockout by entering the patient ID number twice. If you do not want the override to be activated, leave the option unchecked.
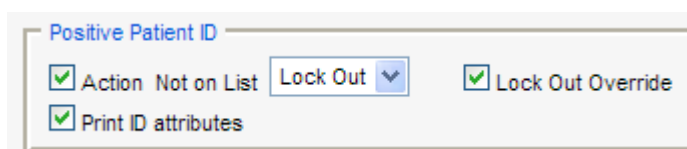
8. Using the drop down menu, select the Confirmation Method the operator will use to confirm the patient identity:
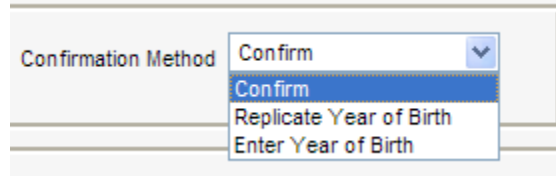
- Confirm: The operator confirms the patient ID by selecting "Continue".

- Replicate Year of Birth: The operator enters the four digits of the patient's year of birth to confirm the patient ID. The date of birth is displayed on the handheld screen.

- Enter Year of Birth: The operator enters the four digits of the patient's year of birth to confirm the patient ID. The date of birth **is not** displayed on the handheld screen.

9. Check the box next to **Print ID attributes** if you want secondary patient identifiers (Name, DOB, Gender) printed with test results on the i-STAT or Martel printers.
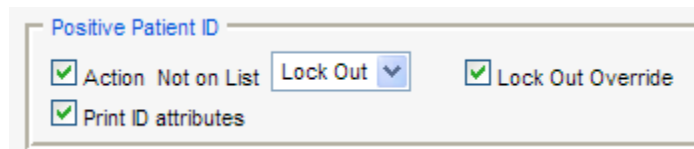
10. Once all options have been chosen, click **OK** and answer **OK** to the question about changing the Preferences.
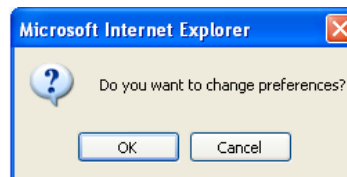
11. If you want to configure the PPID settings for handhelds from other locations, return to step 4. Otherwise, proceed to step 12.
    Download each desired handheld from a downloader in the location to which the handheld is assigned. This action will upload the chosen customization features into the handheld.

CONFIRMING THAT THE PATIENT LIST HAS BEEN TRANSFERRED TO THE i-STAT 1 HANDHELD FROM i-STAT/DE

1. Power on the i-STAT 1 handheld and press **MENU** once to get to the Administration Menu.

2. Press **4 -Customization.**

```
14:36 26JUL11

Administration Menu

1-Analyzer Status
2-Data Review
3-Quality Tests
4-Customization
5-Set Clock
6-Transmit Data
7-Utility
```

3. Press **1-View.**.

```
Customization
  11726BP9

  1-View
  2-Change
```

4. Press **2-ID Entry**.

```
     View
 Customization

 1-Analyzer
 2-ID Entry
 3-Patient Tests
 4-QC Tests
 5-Results
```
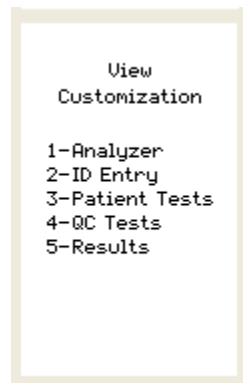
5. Press **2-Patient ID**.

```
        View
    Customization
      ID Entry

    1-Operator ID
    2-Patient ID
```

6. Press the → key twice to view the Patient List Number that has been transferred to the handheld.

```
      Patient ID
    Customization
  Code 39
  Enabled
  Full ASCII
  Code 39
  Check Digit
  Enabled
  Truncate First
  0 digits
  Truncate Last
  0 digits
  Patient List
  120126142043120
    ←   Page   →
```

i-STAT®
TECHNICAL BULLETIN

OPERATOR COMPETENCY NOTIFICATION ON THE i-STAT 1 HANDHELD

OVERVIEW

As part of the on-going READi initiative (**R**esponds, **E**nhances, **A**nd **D**elivers **I**nnovation), Abbott Point of Care (APOC) has released the Operator Competency Notification feature for the i-STAT 1 handheld. This feature allows a system administrator (e.g., Point of Care Coordinator or Laboratory Administrator) to define a time period in which the operator will be notified by a message on the i-STAT 1 handheld display of their competency expiration date.   By default, the feature is turned off.

Functionality

The system administrator will define a time period of notification in the Customization Workspace of the data management system.   When the operator scans or enters their operator ID in the i-STAT 1 handheld, if their competency certification will expire within the timeframe set by the system administrator, a message will appear on the handheld display alerting them of the expiration date.

```
        Operator ID
          12345
        Certification
          Expires
         15MAY17

        1 - Continue
```
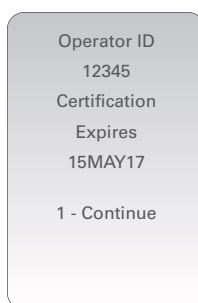
GENERAL CONSIDERATIONS

In order to create Operator Competency Notifications, users must have the i-STAT 1 handheld and either the Central Data Station Version 5 or i-STAT / DE data management applications. <u>This feature is not customizable through the i-STAT 1 handheld keypad</u>.

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Art: 730292-00B   Rev. Date: 13-FEB-17

CUSTOMIZING OPERATOR COMPETENCY NOTIFICATION ON THE i-STAT 1 HANDHELD USING CDS VERSION 5.27a AND ABOVE

Note: Abbott Point of Care recommends that customers use the current version of Central Data Station.

1. Open the Customization Workspace.

2. If the location to which this handheld is assigned has a check mark under the **Use Default Profile** column, double click the alphanumeric code under **Preferences** in the **Default Customization Profile** column. Otherwise, double click the alphanumeric code under **Preferences** for the specific location to which this handheld is assigned.

3. Once the **Preferences** window opens, click on the **ID Entry** tab.

4. In the **Operator ID** section, check the **Expiration Notification** box and type in the number of days (between 1 and 255) in which the operator will be notified of their certification expiration.

5. Click **OK** and then answer **YES** to the question about changing the Preferences.

6. Download the handheld(s) to the CDS from a downloader in the location to which the handheld is assigned. This action should upload the Competency Notification feature into the handheld. Repeat step 6 for all handhelds from the same location to be customized. To customize handhelds from other locations for the same features, return to step 1.

CUSTOMIZING OPERATOR COMPETENCY NOTIFICATION ON THE i-STAT 1 HANDHELD USING i-STAT / DE 2.3

Note: Abbott Point of Care recommends that customers use the current version of i-STAT / DE software.

1. Access the Customization Workspace.

2. If the location to which this handheld is assigned has a check mark under the **Use Default Profile** column, double click the alphanumeric code under **Preferences** in the **Default Customization Profile** column. Otherwise, double click the alphanumeric code under **Preferences** for the specific location to which this handheld is assigned.

3. Once the **Preferences** window opens, click on the **Instrument** tab.
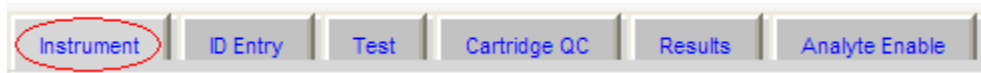
4. In the **i-STAT Reserved** Data section, type "CE=XXX", where XXX indicates the number of days (between 1 and 255) in which the operator will be notified of their certification expiration.

5. Click **OK** and then answer **YES** to the question about changing the Preferences.

6. Download the handheld(s) to i-STAT / DE from a downloader in the location to which the handheld is assigned. This action should upload the chosen customization features into the handheld. Repeat step 6 for all handhelds from the same location to be customized. To customize handhelds from other locations for the same features, return to step 1.

CUSTOMIZING OPERATOR COMPETENCY NOTIFICATION ON THE i-STAT 1 HANDHELD USING i-STAT / DE > 2.3

Note: Abbott Point of Care recommends that customers use the current version of i-STAT / DE software.

1. Access the Customization Workspace.

2. If the location to which this handheld is assigned has a check mark under the **Use Default Profile** column, double click the alphanumeric code under **Preferences** in the **Default Customization Profile** column. Otherwise, double click the alphanumeric code under **Preferences** for the specific location to which this handheld is assigned.

3. Once the **Preferences** window opens, click on the **ID Entry** tab.

4. In the **Operator ID** section, check the **Expiration Notification** box and type in the number of days (between 1 and 255) in which the operator will be notified of their certification expiration.

5. Click **OK** and then answer **YES** to the question about changing the Preferences.

6. Download the handheld(s) to i-STAT / DE from a downloader in the location to which the handheld is assigned. This action should upload the chosen customization features into the handheld. Repeat step 6 for all handhelds from the same location to be customized.
    To customize handhelds from other locations for the same features, return to step 1.

SPECIMEN COLLECTION

Overview   The specimen used to fill a cartridge must be collected and handled properly to ensure that the results represent the patient's current status.

Specimens should be collected according to the facility's policies and procedures. The following precautions (taken from the references at the conclusion of this section) can help avoid potential sources of error prior to filling a cartridge or applying sample to a test strip.

VENIPUNCTURE - GENERAL

Overview   Venipunctures are typically performed for:

- acid-base balance

- electrolyte studies

- metabolic studies

- coagulation studies

- hematologic studies

Observe the following precautions:

I.V. Line   Avoid drawing from an arm with an I.V. line. I.V. solutions will dilute the sample and may interfere with the tests.

Tourniquet   Venous stasis (prolonged tourniquet application) and forearm exercise may increase ionized calcium due to a decrease in pH caused by localized production of lactic acid.

If a tourniquet is applied for more than one minute while looking for a vein, release and reapply after two to three minutes.

Allow the tourniquet to remain in place until all blood is withdrawn to prevent changes in ionized calcium and pH results.

Muscle Activity   Avoid extra muscle activity, such as clenching and unclenching the fist, which may increase potassium results.

Hemolysis   Avoid hemolysis (bursting of red cells) by

- allowing residual alcohol to dry over the puncture site

- discarding a sample from a traumatic draw.

Hemolysis will cause an increase in potassium results and a decrease in calcium results. For cTnI, CK-MB, and BNP cartridges, gross hemolysis can also cause a decreased alkaline phosphatase activity and an increased proteolytic activity, resulting in decreased detection of cTnI, CK-MB, or BNP.

Tube Order   Collect blood collection tubes in the prescribed sequence to avoid interference due to carry-over of additive from one tube to the next:

- No additive

- Citrate

- Heparin

- EDTA - Na_2, K_3 or K_2

- Oxalate, fluoride, iodoacetate

If a citrate tube is drawn, draw a 5 mL plain discard tube before drawing the heparin tube.

VENIPUNCTURE - pH, PCO_2, ELECTROLYTE, CHEMISTRY, AND HEMATOCRIT TESTS

Anticoagulants   If the sample can be tested in a cartridge immediately, a plain syringe can be used. If a cartridge cannot be filled immediately the sample should be collected in a blood collection tube with lithium heparin or a pre-heparinized syringe labeled for measurement of electrolytes and ionized calcium (such syringes contain balanced or low-level heparin). If manually heparinizing syringes, the heparin-to-blood ratio should not exceed 10 U heparin per milliliter of blood. Blood collection tubes contain approximately 15 U/mL when filled to capacity.

Samples collected in EDTA anticoagulant may be used only with the i-STAT Glucose and BNP cartridges. It may be convenient to collect a single EDTA tube when testing for glucose and glycated hemoglobin (HbA1c) simultaneously. **EDTA may not be used with any cartridge type other than the Glucose or BNP cartridges.** EDTA will cause a clinically significant error in sodium, potassium, chloride and hematocrit results and may affect other chemistry tests. Do not use an EDTA sample with a cartridge that includes glucose as part of a panel. Even if only the glucose result is to be used, all results are stored in the analyzer's memory and, since results can be printed and transmitted to a Central Data Station, they can become part of the patient's permanent record.

i-STAT BNP cartridges require the use of EDTA whole blood or plasma samples collected in plastic syringes or evacuated tubes containing EDTA. The use of glass vessels is not recommended because the BNP molecule has been shown to be unstable in glass tubes. The use of whole blood or plasma samples containing other anticoagulants such as heparin, oxalate, and citrate is not recommended.

i-STAT cTnI and CK-MB cartridges require the use of either:

1. heparinized whole blood or plasma samples collected in syringes or evacuated tubes containing lithium or sodium heparin, or

2. non-heparinized whole blood samples tested within one minute of drawing from a patient into a plastic syringe or plastic evacuated tube containing no additives.

   The use of whole blood or plasma samples containing other anticoagulants such as EDTA, oxalate, and citrate will cause deactivation of the alkaline phosphatase, resulting in decreased cTnI or CK-MB readings.

i-STAT Total β-hCG cartridges require the use of:

1. heparinized whole blood or plasma samples collected in plastic syringes or evacuated tubes containing lithium or sodium heparin filled to capacity

   The use of whole blood or plasma samples containing other anticoagulants such as EDTA, oxalate, and citrate will cause deactivation of the alkaline phosphatase, resulting in decreased β-hCG readings.

i-STAT CHEM8+ cartridges require the use of:

1. whole blood collected in non-heparinized evacuated tubes, or syringes, as long as sample is tested immediately upon draw,

2. heparinized whole blood collected in balanced heparin syringes or capillary tubes, or

3. heparinized whole blood collected in evacuated tubes containing lithium heparin, as long as the tubes are filled to capacity.

Fill Requirements

Fill blood collection tubes with *and without* anticoagulant and syringes with anticoagulant to capacity. Incomplete filling of anticoagulated tubes and syringes will cause higher heparin-to-blood ratios, which will decrease ionized calcium results and may affect other results. Under filling blood collection tubes with *and without* anticoagulant may also cause decreased $P\text{CO}_2$, HCO_3 and TCO_2 results.

Partial-draw blood collection tubes (evacuated tubes that are adjusted to draw less than the tube volume, e.g. a 5 mL tube with enough vacuum to draw only 3 mL), with *or without* anticoagulant, are not recommended for blood gas or CHEM8+ cartridge analysis because of the potential for decreased $P\text{CO}_2$, HCO_3 and TCO_2 results. Care must also be taken to eliminate "bubbling" of the sample with a pipette when filling a cartridge to avoid the loss of CO_2 in the blood.

Mixing

Gently mix blood (whether anticoagulated or not) immediately to avoid clotting. Invert a blood collection tube at least 10 times. Roll a syringe vigorously between the palms for at least 5 seconds each in two different directions, then invert the syringe repeatedly for at least 5 seconds, then discard the first two drops of blood. Note that it may be difficult to properly mix a sample in a 1.0 cc syringe.

Exposure to Air	Avoid exposing the sample to air when testing venous samples for ionized calcium, pH, PCO_2 and TCO_2. Test immediately if the sample is drawn into a blood collection tube. Expel any air bubbles immediately if the sample is drawn into a syringe or leave an air bubble next to the plunger and do not allow it to move through the sample.
Time to Test	For the most accurate results, test samples immediately after drawing. Samples for lactate must be tested immediately. Samples for pH, PCO_2, PO_2, TCO_2, and ionized calcium should be tested within 10 minutes. Other analytes should be tested within 30 minutes.
	If testing is not immediate, remix blood collection tubes by gentle inversion at least 10 times. Roll syringes between the palms for at least 5 seconds each in two different directions, then invert the syringe repeatedly for at least 5 seconds, and then discard the first two drops of blood. Blood in the tip of the syringe may have been exposed to air and may not be homogenous with the sample in the barrel of the syringe. Note It may be difficult to properly remix a sample in a 1.0 cc syringe.

VENIPUNCTURE - COAGULATION TESTS

Blood Flow	Collection technique resulting in good blood flow must be used. Inadequate blood flow may produce erroneous results.
Plastic	The sample for testing should be drawn into a **plastic** collection device (syringe or blood collection tube) containing **no anticoagulant, clot activators, or serum/plasma separators**. Any transfer device (dispenser, capillary tube, pipette or syringe) **must be plastic** and must **not contain anticoagulant**.
	Samples collected into glass tubes or syringes, or in tubes containing anticoagulants, activators, or separators cannot be used with the i-STAT coagulation cartridges.
	Note: CLSI guidelines recommend that the sample for coagulation testing be the second or third tube drawn when using a blood collection system (use a discard tube if this is the only sample being drawn) or be taken from the second syringe if a double syringe technique is used for drawing blood.
Time to Test	The sample must be immediately dispensed into the sample well of the cartridge and the cartridge must be inserted immediately into an analyzer.
Repeat Test	If a repeat measurement is needed, a fresh sample must be obtained.

ARTERIAL PUNCTURE - GENERAL

Overview	Arterial punctures are performed to access gas exchange status.
	PCO_2, PO_2, and pH values change with changes in ventilatory support at a rate dependent on underlying conditions. Sample should be drawn after these changes have stabilized.

ARTERIAL PUNCTURE - BLOOD GAS, ELECTROLYTE, CHEMISTRY, AND HEMATOCRIT TESTS

Evacuated Tubes

Evacuated or other blood collection tubes are not recommended for blood gas analysis.

Syringes and Anticoagulant

If the sample can be tested in a cartridge immediately, a plain syringe can be used.

If a cartridge cannot be filled immediately, the sample should be collected in a pre-heparinized syringe labeled for measurement of electrolytes and ionized calcium (such syringes contain balanced or low-level heparin).

If manually heparinizing syringes, the heparin-to-blood ratio should not exceed 10 U heparin per milliliter of blood.

Fill syringes to the recommended capacity or use the least amount of liquid heparin anticoagulant that will prevent clotting. Under filling syringes will cause higher heparin-to-blood ratios which will decrease ionized calcium results due to binding. Under filling syringes with liquid heparin will also dilute the sample causing results to be affected.

i-STAT BNP cartridges require the use of EDTA whole blood or plasma samples collected in plastic syringes or evacuated tubes containing EDTA. The use of glass vessels is not recommended because the BNP molecule has been shown to be unstable in glass tubes. The use of whole blood or plasma samples containing other anticoagulants such as heparin, oxalate, and citrate is not recommended.

i-STAT cTnI and CK-MB cartridges require the use of either:

1. heparinized whole blood or plasma samples collected in syringes or evacuated tubes containing lithium or sodium heparin, or

2. non-heparinized whole blood samples tested within one minute of drawing from a patient into a plastic syringe or plastic evacuated tube containing no additives.

    The use of whole blood or plasma samples containing other anticoagulants such as EDTA, oxalate, and citrate will cause deactivation of the alkaline phosphatase, resulting in decreased cTnI or CK-MB readings.

i-STAT CHEM8+ cartridges require the use of:

1. whole blood collected in non-heparinized evacuated tubes, or syringes, as long as sample is tested immediately upon draw,

2. heparinized whole blood collected in balanced heparin syringes or capillary tubes, or

3. heparinized whole blood collected in evacuated tubes containing lithium heparin, as long as the tubes are filled to capacity.

Mix	Mix blood (whether anticoagulated or not) by rolling between the palms for at least 5 seconds, each in two different directions. Then invert the syringe repeatedly for at least 5 seconds. Discard the first 2 drops of blood.
Exposure to Air	Avoid or remove immediately any air drawn into the syringe and maintain anaerobic conditions.
Time to Test	For the most accurate results, test samples immediately after draw. Samples for lactate must be tested immediately. Samples for pH, $P\text{CO}_2$, $P\text{O}_2$, $T\text{CO}_2$, and ionized calcium should be tested within 10 minutes. Other analytes should be tested within 30 minutes.
	If testing is not immediate, remix the syringe by rolling between the palms for 5 seconds each in two different directions, then invert the syringe repeatedly for at least 5 seconds, then discard the first two drops of blood. Blood in the tip of the syringe may have been exposed to air and may not be homogenous with the sample in the barrel of the syringe. Note that it may be difficult to properly remix a sample in a 1.0 cc syringe.
Sample on Ice	Fill the cartridge before icing the sample for transport. Icing will increase the potassium and will affect oxygen levels in samples collected in plastic syringes.

ARTERIAL PUNCTURE - ACT TESTS

Blood Flow	Collection technique resulting in good blood flow must be used. Inadequate blood flow may produce erroneous results.
Plastic	The sample for testing should be drawn into a **plastic** collection device (syringe or blood collection tube) containing **no anticoagulant**.
	Samples collected into glass tubes or syringes, or in tubes containing anticoagulants, cannot be used with the i-STAT coagulation cartridges.
	Note: CLSI guidelines recommend the sample for coagulation testing be the second or third tube drawn when using a blood collection system (use a discard tube if this is the only sample being drawn) or be taken from the second syringe if a double syringe technique is used for drawing blood.
Time to Test	The sample must be immediately dispensed into the sample well of the cartridge and the cartridge must be inserted immediately into an analyzer.
Repeat Test	If a repeat measurement is needed, a fresh sample must be obtained.

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INDWELLING LINE

Blood Gas, Electrolyte, Chemistry	Back flush line with a sufficient amount of blood to remove intravenous solutions, heparin or medications that may contaminate the sample. Five to six times the volume of the catheter, connectors and needle is recommended.
Coagulation Cartridges	If blood **must** be drawn from an indwelling line, possible heparin contamination and specimen dilution should be considered. The line should be flushed with 5 mL of saline and the first 5mL of blood or six dead space volumes of the catheter should be discarded.

SKIN PUNCTURE

Device	Use a puncture device that provides free-flowing blood. Inadequate blood flow may produce erroneous results.
Blood Gas Analysis	There are conflicting reports in the literature regarding the validity of PO_2 analysis performed on arterialized skin puncture specimens compared to arterial PO_2. The process of capillary collection may change PO_2, PCO_2, and the calculated sO_2. Arterial specimens are preferred for blood gas analysis. See CLSI documents H4-A5, C-46A, and H11-A4 listed in the References section for further discussion.
Hemolysis	Avoid hemolysis (bursting of red cells) due to vigorous massaging or "milking."
	Hemolysis will cause an increase in potassium results and a decrease in calcium results.
	To increase blood flow, massage a finger gently from about three inches from the tip to the fleshy portion of the tip.
	Avoid hemolysis by allowing residual alcohol to dry over the puncture site.
Tissue Fluid	For tests other than PT/INR cartridges, wipe away the first drop of blood as it may contain excess tissue fluid, which can increase potassium results, and decrease the other test results.
Air	Avoid drawing air into the capillary tube.

Anticoagulant	Most heparinized capillary tubes are not suitable for electrolyte measurements, especially ionized calcium, due to the high concentration of heparin (50 U/mL or more). Use balanced heparin tubes.
Time to Test	Test samples collected in capillary tubes immediately to avoid clotting (especially in neonates whose blood may clot more quickly).
Warming Area	Blood flow can be stimulated by warming the puncture site. Follow the facility's policy and procedure for warming (arterializing) an infant's heel or other skin puncture area.
ACT, cTnI, CK-MB, β-hCG and BNP Cartridges	**Skin puncture samples are not recommended for ACT, cTnI, CK-MB, β-hCG and BNP measurements.**
PT/INR Cartridges	i-STAT PT/INR cartridges should be filled directly from the puncture site by allowing blood to flow from the site into the cartridge - no transfer device should be used.

SAMPLE TRANSFER DEVICES

Dispensers	A dispenser can be used to avoid the use of needles when transferring a blood sample from a blood collection tube.

Do not use dispensers that would introduce air into the sample when ionized calcium, pH, or PCO$_2$ are being measured.

For coagulation testing the dispenser **must be plastic** and must **not contain anticoagulant**. |
| **Capillary Tube** | While a sample can be transferred directly from a skin puncture to a cartridge, a capillary tube is preferred.

Capillary tubes can be used to transfer sample from a tube to a cartridge. For coagulation testing, the capillary tube **must be plastic** and must **not contain anticoagulant**. |
| **Syringe** | A 1cc syringe (such as a tuberculin) and needle (no smaller than 20 gauge) can be used to withdraw a sample from an blood collection tube.

Take care not to draw air with the sample when ionized calcium, pH, PCO$_2$, or TCO$_2$ are being measured.

For coagulation testing, the syringe **must be plastic** and must **not contain anticoagulant**. |

REFERENCES

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PREPARATION FOR TESTING

Select the Cartridge Select the appropriate cartridge for the test or tests required. While the cartridge is not fragile, it should be handled as follows to avoid difficulty in filling and Quality Check failures.

Room Temperature Each cartridge is sealed in a foil pouh or clear plastic portion pack for protection during storage. A cartridge should not be removed from its protective pouch until it is at room temperature (18-30 °C or 64-86 °F). For best results, the cartridge and analyzer should be at the temperature of the room where they are to be used. Condensation on a cold cartridge may prevent proper contact with the analyzer. Allow a single cartridge to stand for 5 minutes and a box of cartridges for 1 hour at room temperature before use. Use a cartridge immediately after removing it from its protective pouch — prolonged exposure may cause a cartridge to fail a Quality Check. If the pouch has been punctured, the cartridge should not be used. Once cartridges have been brought to room temperature, they should not be returned to the refrigerator. Cartridges may be stored at room temperature for the time frame indicated on the cartridge box.

Contact Pads and Sensors Avoid touching the contact pads, as this may cause contamination and prevent the analyzer from making proper contact with the cartridge. Avoid touching the sensors on the top.

Calibrant Pack Do not apply pressure to the central area of the label as the calibrant pack inside could burst prematurely.

Air Vent Do not block the air vent as the sample will not flow to the fill mark and the calibrant solution will not flow to the sensors.

Contamination To avoid contaminating the analyzer do not use a cartridge on which blood or any other fluid has spilled. Avoid filling cartridges on surfaces that may cause the cartridge to pick up fibers, fluid or debris that may lodge in the analyzer.
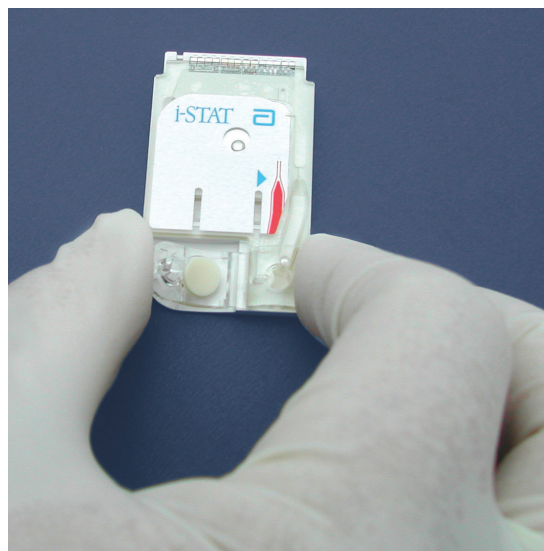
FILLING AND SEALING CARTRIDGE

Procedure	STEP	ACTION

| | 1 | Place the cartridge on a flat surface. Note the location of the sample well and fill mark indicator, as identified in the images below. |

Fill Mark Indicator

Sample Well

Sample Well

| | 2 | **Mix the sample thoroughly.** |

    a. Invert a blood collection tube at least 10 times.

    b. Roll a syringe repeatedly between the palms for at least 5 seconds each in two different directions, then invert the syringe repeatedly for at least 5 seconds. Note that it may be difficult to properly mix a sample in a 1.0 cc syringe

    c. Expel a few drops of sample from the transfer device before filling the cartridge

| | 3 | Direct the tip of the transfer device (syringe, capillary tube, pipette, or dispensing tip)* into the sample well/inlet port, as shown below. |

Note: **Not directing the transfer device into the sample well could result in a sample not filling the cartridge or pooling on the sample well/inlet port**
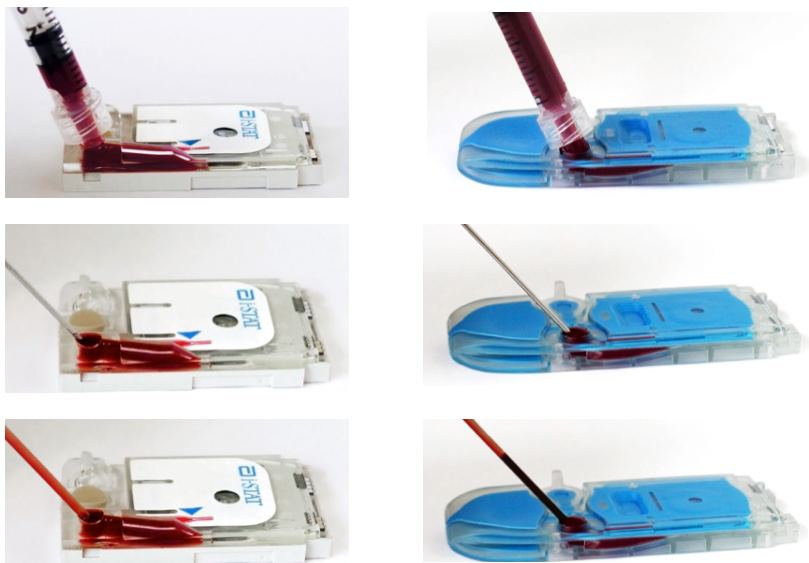
*For a complete list of recommended transfer devices, refer to Section 10 -Sample Collection of the i-STAT1 System Manual.

Procedure	STEP	ACTION
	4	Dispense a small amount of sample, ensuring it travels toward the fill mark before applying additional sample. Avoid creating a bubble on the sample well. a. Continue dispensing until the sample reaches the fill mark indicated on the cartridge b. Ensure that there is sample in the inlet port, as well as the sample chamber

**Properly Filled Cartridge
(cTnI, CK-MB, β-hCG and BNP)**

These images display a properly filled cartridge. In the images at the top, the sample fills the sample chamber to the fill mark indicator.

Notice the images on the bottom show a full sample well, and no bubble appears in the sample pathway.

**Properly Filled Cartridge
(Chemistry/Electrolyte/Blood Gas)**

These images display a properly filled cartridge. In the images at the top, the sample fills the sample chamber to the fill mark indicator.

Notice the images on the bottom show a full sample well, and no bubble appears in the sample pathway.

Procedure	STEP	ACTION
	5	Fold the snap closure over the sample well:

     a. Keeping your thumb or finger on the outside edge of the closure clasp, press the rounded end of the closure until it snaps into place

     b. Ensure that the cartridge is completely closed before inserting it into the device

To close the immunoassay cartridge with the plastic closure clip:

     a. First anchor the cartridge in place by using the thumb and index finger of one hand to grasp the cartridge from its side edges away from the sample inlet.

     b. Use the thumb of the other hand to slide the plastic closure clip to the right until it locks into place over the sample well.

Properly Closed Cartridge
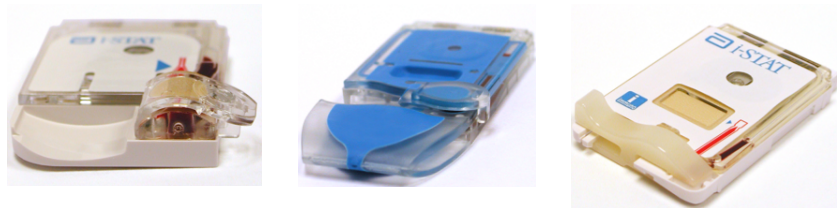
These images display properly filled and closed cartridges. As such, they may be inserted into the handheld.

Examples of Overfilled Cartridges

These images display overfilled cartridges. In the images at the top, the sample exceeds the fill mark indicator. In the images at the bottom, you will notice a bubble in the sample well.

Every effort should be made to fill cartridges properly before inserting into the handheld device.

Examples of Under-filled Cartridges
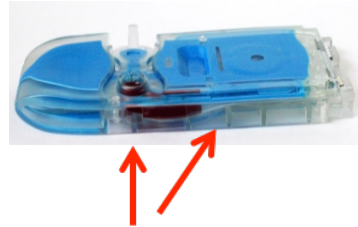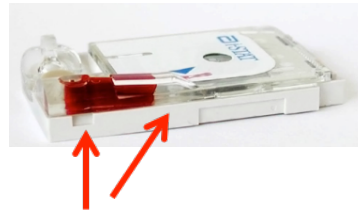
These images display under-filled cartridges. In the images on the left, the sample well is insufficiently filled, and the sample does not reach the fill mark indicator.

In the images on the right, the sample well is sufficiently filled, but the sample does not reach the fill mark indicator.

Every effort should be made to fill cartridges properly before inserting into the handheld device.

Examples of Improperly Closed Cartridges

These images display improperly closed cartridges. Although they were properly filled, they must be closed sufficiently before they may be inserted into the device.

FILLING AND SEALING PT/INR (PROTHROMBIN TIME) CARTRIDGES USING DIRECT FINGERSTICK SAMPLING

STEP	ACTION
1	Remove cartridge from foil pouch and place the cartridge on a flat surface.
2	Prepare lancet device and set aside until needed.
3	Clean and prepare the finger to be sampled using a 70% aqueous solution of isopropanol (70% v/v). Allow the finger to dry thoroughly before sampling. When disinfecting fingerstick skin puncture sites, swabs or solutions containing substances other than isopropanol (e.g. Chlorhexidine Gluconate) are not recommended. Refer to the "Limitations of the i-STAT PT/INR Test" section in the PT/INR Cartridge and Test Information Sheet for more information.
4	Prick the bottom side of the fingertip with the lancet device.
5	Gently squeeze the finger, developing a hanging drop of blood and perform the test with the first sample of blood. *Avoid strong repetitive pressure ("milking") as it may cause hemolysis or tissue fluid contamination of the specimen.*
6	Touch the drop of blood against the bottom of the sample well. Once in contact with the sample well, the blood will be drawn into the cartridge.
7	Apply sample until it reaches the fill mark indicated on the cartridge.
8	Fold the sample closure over the sample well.
9	Press the rounded end of the closure until it snaps into place. Slightly lift finger or thumb and ensure that the cartridge is closed before completely removing finger or thumb from the closure.

Note: To further simplify the sample application into the test cartridge, it is possible to bring the cartridge to the finger for easier application. Do ensure that the instrument remains on a flat, vibration-free surface for testing.

INSERTING AND REMOVING THE CARTRIDGE FROM THE ANALYZER

STEP   ACTION

Inserting Cartridge into Analyzer

1   Align the cartridge with the contact pads facing up and toward the cartridge port.

2   Push the cartridge slowly and smoothly into the cartridge port until it clicks into place.

Removing Cartridge from Analyzer

3   Do not attempt to remove the cartridge while the message "Cartridge Locked" remains on the screen.

4   When results are displayed, pull the cartridge straight out of the analyzer.

5.   Dispose of the cartridge in a container for biohazards, following local, state, and national regulatory guidelines.

INCORRECT PROCEDURE

Overview　　　The cartridge is designed to fill and seal correctly. However, the conditions described below may occur, especially during the training period. If the condition is not detected by the operator, the analyzer will detect the condition, halt the test cycle and display a cause message followed by the action message "USE ANOTHER CARTRIDGE."

Condition	Operator Action	Analyzer Display
Sample beyond fill mark.	If the sample flows only slightly beyond the fill mark, the cartridge can still be used. If the sample is close to or enters the air segment chamber, use another cartridge.	SAMPLE POSITIONED BEYOND FILL MARK
Sample not up to fill mark.	If the sample well fills but the sample does not reach the fill mark, ensure that the air vent (small hole on the underside of the cartridge) is not blocked. Tilt the cartridge slightly so that gravity aids the flow. When the sample starts to flow into the chamber, return the cartridge to the horizontal position. If the sample is considerably short of fill mark, the analyzer will detect the condition and halt the test cycle.	SAMPLE POSITIONED SHORT OF FILL MARK
Sample well empty.	If the sample reaches the fill mark, but the sample well is left completely empty, there may be insufficient sample for the test.	INSUFFICIENT SAMPLE
Air bubbles in sample.	If air bubbles are trapped in the sample chamber, discard the cartridge and fill another.	INSUFFICIENT SAMPLE
Sample well overfilled.	If the sample well is so full that sample is seen above the sample well after the sample chamber is filled, do not wipe or absorb the excess with a gauze or tissue but draw the excess back into the syringe or a capillary tube. If the sample spreads over the outside of the sample well, an airtight seal may not form when the cartridge is closed. In this case the analyzer may not be able to move or position the sample over the sensors.	UNABLE TO POSITION SAMPLE
Sample clotted.	If the sample clots in the sample well the analyzer will not be able to move or position the sample over the sensors.	UNABLE TO POSITION SAMPLE
Cartridge contaminated.	If sample spills onto the cartridge or if the cartridge has collected debris, discard the cartridge. Inserting a contaminated cartridge into the analyzer will cause debris to build up on the pins that contact the cartridge pads which will cause a cartridge or analyzer Quality Check code.	CARTRIDGE ERROR or ANALYZER ERROR
Sample pushed beyond fill mark.	Avoid applying excess pressure on the closure directly over the sample well as doing so may push the sample beyond the fill mark.	SAMPLE POSITIONED BEYOND FILL MARK
Cartridge sealed before sample reaches fill mark.	Closing the cartridge before the sample chamber has filled will stop the flow of the sample to the fill mark.	SAMPLE POSITIONED SHORT OF FILL MARK
Cartridge not sealed before inserted into analyzer.	Failure to close the cartridge before inserting it into the analyzer will prevent sample movement and can cause the sample to flow backward and out of the sample well.	UNABLE TO POSITION SAMPLE.

Caution

The following cautions should be taken to prevent damage to the analyzer and to ensure the safety of the operator and the integrity of results.

- Never look into the barcode scanner beam or point it toward anyone's eyes. The beam could cause permanent eye damage.

- Do not attempt to remove a cartridge during the testing cycle. The force that would be necessary to do so could damage the analyzer. The message "Cartridge Locked" will remain on the screen until the analyzer unlocks the cartridge.

- The analyzer may be contaminated with blood from prior use. Whenever handling the analyzer, cartridges, and peripherals exercise universal precautions to protect yourself from blood-borne pathogens. Universal precautions are those procedures and practices, such as the wearing of gloves, designed to protect personnel from blood-borne pathogens as well as pathogens from other body substances. These precautions are based on the assumption that blood, body fluids or tissue can contain infectious agents and, therefore, should be treated as a biohazard. For more detailed information, please refer to either the CDC/NIH manual, "Biosafety in Microbiological and Biomedical Laboratories", Fifth Edition, 2009, or the WHO "Laboratory Biosafety Manual", Third Edition, 2004.

  To protect from nosocomial infections, decontaminate analyzers periodically and whenever blood is spilled or transferred to an analyzer. See under "Cleaning the Analyzer and Downloader" in section 17 of this manual.

- A falling analyzer may cause injury. Always place the analyzer and peripherals on a stable surface or in a location where it will not cause injury if dropped.

- The analyzer may be rendered inoperative by damage due to mishandling, such as dropping, by exhausting the batteries or by other causes. Clinical settings that demand fail-safe testing should reduce this risk by having a backup analyzer or test source available.

- The analyzer should not be used in environmental conditions that exceed the operating temperature and humidity specifications. An analyzer that has been exposed to extreme environmental conditions must be allowed to come to equilibrium with the operating environment prior to use. Note: the analyzer will display the message "Temperature Out of Range" until it has reached its operating temperature.

- The analyzer and its peripherals are not listed by any authority with respect to suitability for use in oxygen enriched atmospheres.

- Proper procedure must be used to ensure correct manual entry of patient ID, operator ID, sample type and other data that may affect the clinician's interpretation of results.

- **DO NOT insert cartridge to start test.**

- **DO NOT open cartridge pouch before scanning the barcode.**

- **If Quality Check Code 69 or 140 appears, see Analyzer Coded Messages Technical Bulletin for Troubleshooting Information.**

1. Press ⏻ to turn on the handheld.

2. Press ② for i-STAT cartridge.

3. Follow the handheld prompts.

4. Scan the lot number on the cartridge pouch.

   - Position barcode 3-9 inches from scanner window on the handheld.

   - Press and hold SCAN to activate the scanner.

   - Align the red laser light so it covers the entire barcode.

   - The handheld will beep when it reads the barcode successfully.

5. Continue normal procedures for preparing the sample, and filling and sealing the cartridge.

6. Push the sealed cartridge into the handheld port until it clicks into place. Wait for the test to complete.

Note: For ACT, PT/INR, Hct, and immunoassay testing, the handheld must remain on a level surface with the display facing up during testing. A level surface includes running the handheld in the downloader/recharger.

7. Review results.
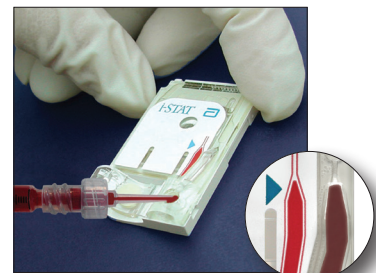
INTERPRETATION OF DISPLAYED RESULTS

Results Display

Test results are displayed with numerical concentration values in the units selected for the Customization profile. For patient test results, bar graphs depicting the values in relation to reference ranges are also displayed. Reference ranges are marked on the bars by tic marks. When all test values are within their reference ranges, the tic marks will be centrally aligned. The bar graphs can be used as a visual cue for distinguishing between "normal" and "abnormal" results. Blood gas, coagulation, and immunoassay results are not displayed with bar graphs and reference ranges.

If a value exceeds the reference range, the bar graph may be rescaled to show the reference range and value in relation to the measurement range.

```
Pt: 221222222
13:07 21AugYY
i-STAT EC8+

Na mmol/L        141
K mmol/L         4.5
Cl mmol/L        101
TCO2 mmol/L       27
BUN mg/dL         12
Glu mg/dL        106
Hct %PCV          41

➡ Page
```

Reportable Ranges

The reportable range (sometimes referred to as the linear range) is the concentration range over which test results are valid. Reportable ranges programmed into the analyzer are listed in the Cartridge and Test Information section.

Reference Ranges

Reference ranges (sometimes referred to as normal ranges) in the default Customization profile are derived from the literature and are listed in the Cartridge and Test Information section as well as in the Customization option on the analyzer. Variables such as sex, age, heritage and other demographic factors of a population may cause a shift in these ranges. Therefore, it is usually recommended that each facility determine its own reference ranges. Reference ranges can be changed using the Customization function on the Central Data Station or DE.

```
Pt: 22212111
10:11 22AugYY
i-STAT EG7+

37.0°C

pH              7.461
PCO₂ mmHg        27.8
PO₂ mmHg          135
BEecf mmol/L       -4
HCO₃ mmol/L        20
TCO₂ mmol/L        21
sO2%               99

➡ Page
```

Action Ranges

Action ranges (sometimes referred to as critical values) indicate results that require immediate attention. When a test result falls outside the action range it is flagged as either above the high action range ↑ or below the low action range ↓. Action ranges are programmed into the analyzer using the Customization function on the Central Data Station or i-STAT/DE and can be viewed on the analyzer under the Customization option.

```
Pt: 112112211
15:06 20AugYY
i-STAT EC8+

Na mmol/L        139
K mmol/L         7.2↑
Cl mmol/L        101
TCO2 mmol/L       25
BUN mg/dL         12
Glu mg/dL        106
Hct %PCV          40

➡ Page
```

Note: Since the ↑ and ↓ symbols cannot be printed from the Martel Printer, action range flags on a Martel printer will appear with the << >> symbol.

ACT Cartridges

When testing a Celite ACT or Kaolin ACT cartridge, an option to cancel the test will appear on the analyzer screen. The cancel test option will only appear after all the data entry has been completed. If the operator chooses to cancel the test, the result will display as "0".
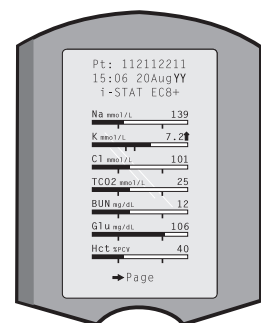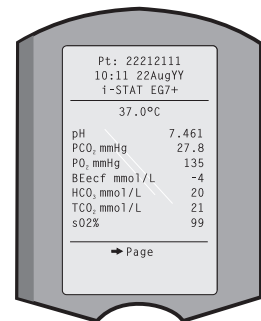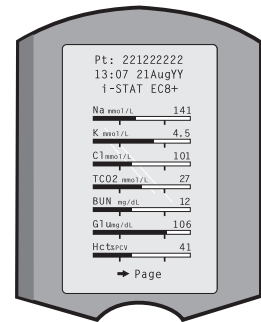
Flags

When the analyzer detects an out-of-range result or an uncharacteristic sensor signal, the condition is indicated by a flag. See table below for flags and symbols used with results. Note: The reportable range flags do not apply when testing is performed under Quality Tests Option **3 – Cal Ver**. Action flags do not apply to Option **1 – Control** or Option **3 – Cal Ver**.
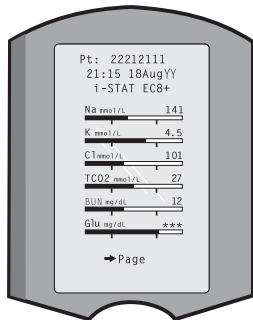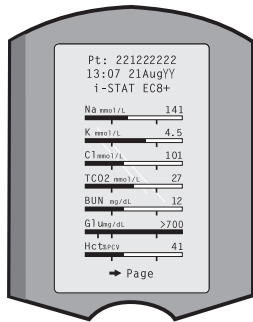
Display	Action	Analyzer Response / Comments
>	*The result falls above the reportable range of the test.*	*If an ACT result is displayed as >1000, the result should be reported as "greater than 1000 seconds."*
<	*The result falls below the low end of the reportable range of the test.*	*If a pH result is displayed as <6.5, the result should be reported as "less than 6.5."*
< >	*This result is dependent on another test that has been flagged.* *The <> flag will also be displayed for TCO_2, pH, **P**CO_2, HCO_3, anion gap, base excess, and sO_2 if the TCO_2 is <1 or >80 mmol/L. Because the values outside this range are essentially non-physiological, the TCO_2 range check is used as an additional quality check on the validity of the underlying pH and **P**CO2 results.*	*If a sodium result is displayed as >180, the calculations for potassium, chloride, BUN/Urea and hematocrit, which depend upon the sodium measurement, will be flagged < >.*
↑	*The result is above the high action range.*	*If the action ranges for potassium are 3.2 and 5.5, a result of 6.0 will be displayed as 6.0 ↑.*
↓	*The result is below the low action range.*	*If the action ranges for potassium are 3.2 and 5.5, a result of 3.0 will be displayed as 3.0 ↓.*
***	*The signals from a particular sensor are uncharacteristic. Uncharacteristic signals can be caused by a compromised sensor or by an interferent in the sample.* *This flag also appears for any test dependent on another test which is flagged with stars.*	*The sample should be retested using another cartridge.* *If the stars reappear, refer to the troubleshooting paragraph in this section of the manual.*

TROUBLESHOOTING

Warning Message   If testing is disabled due to a warning message, the condition must be corrected and the analyzer must be turned off and back on again before testing is enabled.

Message and Quality Check Code   See Troubleshooting section.

*** Instead of Results   Stars appear in place of results if the analyzer detects that the sensor's signal is uncharacteristic. Since the sensor check is part of the i-STAT quality system, an occassional result will be flagged due to a bad sensor. Other causes of this flag are improperly stored cartridges or an interfering substance in the patients sample, either extrinsic, such as the wrong anticoagulant, or intrinsic such as medication. Also, aged samples may contain products of metabolism that can interfere with the tests.

- If the specimen's integrity is not in question, the results that are not suppressed should be reported in the usual manner.

- Check the supply of cartridges in use with a control solution.

- If the control is in range, draw a fresh sample from the patient and retest.

- If the stars appear in place of results again, there may be an interfering substance. Refer to the Cartridge and Test Information section for a list of interfering substances. Test the sample using another method.

- If the control is out-of-range or if stars are displayed in place of results, there may be a problem with the cartridge lot number. Use another lot number or repeat the test using another method, and contact your support representative. (Refer to Support Services information in the Technical Bulletin section.)

Unexpected Results   When results do not reflect the patient's condition, repeat the test using a fresh cartridge and sample. If results are still suspect, test the lot of cartridges in use with i-STAT control solutions. If the controls are in range, there may be an interfering substance in the sample. Check the Cartridge and Test Information sheets for the test in question. Test by another method to verify the result. If the controls are out of range there may be a problem with the cartridge lot number. Use another lot number or repeat the test using another method, and contact your support representative. (Refer to Support Services information in the Technical Bulletin section.)

Upon installation of the April 2012 Software Update, the Glucose Test Strip Port functionality will be permanently disabled on all i-STAT 1 Handhelds.

Note: The remaining technical information regarding the Glucose Strip Port will be removed from the i-STAT 1 System Manual by April, 2013. Please contact your Support Services representative for information on transitioning to an Abbott Diabetes Care blood glucose monitoring system.

Overview

This section describes the steps to be taken to verify the performance of the analyzer and cartridges. The rationale for the i-STAT cartridge and analyzer quality regimen is described in the Theory section of this manual.

Customization

The quality control behavior of the analyzer can be customized via the Central Data Station or analyzer Customization Change function to:

- turn the external Electronic Simulator reminder on or off.
- prompt the operator to use the external Electronic Simulator at scheduled intervals.
- turn the internal Electronic Simulator on or off, and select the simulator test cycle intervals.
- disable further cartridge testing when the internal Electronic Simulator test fails.

See the Customization section for default values.

Data Retention

Quality control data is transmitted to the Central Data Station. If a Central Data Station is not being used, the charts at the end if this section can be used to record liquid and electronic control results.

QUALITY CONTROL FOR i-STAT CARTRIDGES AND THE ANALYZER'S CARTRIDGE TEST CYCLE

Verify Newly Received Cartridges and Control Materials

1. Verify that the transit temperatures were satisfactory using the four-window temperature indicator strip included in the shipping container.
   Note: Controls and calibration verification materials shipped with gel packs will also include a four-window indicator to monitor temperature during transit.

2. From each lot in each shipment of cartridges, analyze multiple levels of i-STAT controls (and TriControls if testing for hematocrit) using any verified analyzer.*

   * This information is not a manufacturer's system instruction. It is a suggestion to comply with regulatory requirements that may pertain to your laboratory.

Verify Performance of Analyzers Daily

Verify the performance of each analyzer on site using the Electronic Simulator (external or internal) once a day on the days the analyzers are in use. Note that regulatory or accreditation requirements may dictate more frequent intervals.

Check Refrigerator Storage Daily

Verify that the cartridges stored in the refrigerator are within the expiration date printed on the boxes.

Verify that the storage refrigerator did not exceed the temperature limits of 2 to 8 °C (35 to 46 °F). If storage conditions are in doubt, use controls to verify that the cartridges are performing properly. This is especially important if freezing conditions are suspected at the back of the refrigerator.

Check Room Temperature Storage Daily

Verify that the cartridges stored at room temperature are within the expiration date and that the cartridges have been out of the refrigerator less than the time frame indicated on the cartridge box. If the temperature at which the cartridges are stored is in doubt, use controls to verify that the cartridges are performing properly.

Check Thermal Control System Every Six Months

i-STAT analyzers contain a thermal control subsystem consisting of two thermal probes with thermistors and heating contact wires. When measurements are performed at a controlled temperature, the thermal probes in the analyzer contact the metalized area under the chips in the cartridge and maintain the temperature of the sensors and the fluids that come into contact with these sensors at the required temperature ± 0.15°C.

A quality check is performed on the thermal probes each time the external Electronic Simulator is used. To complete this check, the surface temperature of the external Electronic Simulator must not fluctuate. If this condition is not met, the thermal probe check is not completed. Therefore, i-STAT recommends that the thermal probe check be verified every six months.

CONTROLS FOR BLOOD GAS/ELECTROLYTE/METABOLITE CARTRIDGES

Control Solutions

Aqueous assayed control fluids are available for verifying the integrity of newly received cartridges. i-STAT Level 1, 2 and 3 Controls are formulated at three clinically relevant levels with known pH and with known concentrations of:

Sodium	$P\text{CO}_2$	Glucose
Potassium	$P\text{O}_2$	Lactate
Chloride	TCO_2	BUN/Urea
Ionized Calcium		Creatinine

Each level of control is packaged in a box of 10 ampules. Control solutions are contained in 1.7 mL glass ampules.

The control solutions do not contain human serum or serum products, but do contain buffers and preservatives.

Reactive Ingredients

Analyte	Calibration Verification Level 1	Calibration Verification Level 2 and Control Level 1	Calibration Verification Level 3 and Control Level 2	Calibration Verification Level 4 and Control Level 3	Calibration Verification Level 5
Na (mmol/L)	108	127	141	169	187
K (mmol/L)	2.3	3.1	4.0	6.8	8.5
Cl (mmol/L)	71	85	100	122	133
Glu (mmol/L)	1.8	2.5	7.3	17	35
Urea (mmol/L)	44.6	18	4	2.7	1.8
iCa (mmol/L)	2.5	1.6	1.3	0.8	0.2
Lac (mmol/L)	19.5	8.4	2.3	1	0.6
Crea (µmol/L)	1486	386	155	46	17
$P\text{O}_2$ (mmHg)	43	61	100	140	400
$P\text{CO}_2$ (mmHg)	95	66	30	22	18
H^+ (pH)	6.81	7.15	7.41	7.60	7.95

Storage

Refrigerated storage at 2 to 8 °C (35 to 46 °F) should be maintained until the printed expiration date on the box and ampule labels.

Control solutions may also be stored at room temperature for up to 5 days (18 to 30 °C or 64 to 86 °F). Prolonged storage at temperatures greater than 30 °C (86 °F) may cause changes in the values of some analytes. Do not use beyond the expiration date on the box and ampule labels.

Best Results

For best results, ampules, cartridges and analyzer should be at the same temperature.

Ampule Use

When using cartridges that contain sensors for pH, $P\text{CO}_2$, $P\text{O}_2$ and ionized calcium, a separate ampule must be used for each cartridge being tested.

Do not use the solution left in a syringe, ampule or capillary tube for additional testing of cartridges that contain sensors for ionized calcium, pH, $P\text{CO}_2$, or $P\text{O}_2$. However, cartridges without these sensors may be tested with remaining fluids if within 10 minutes of opening the ampule.

Before Use	i-STAT control solutions require different temperature stabilization times depending on whether or not oxygen is to be measured. If oxygen is to be measured, equilibrate the ampule for 4 hours. If not, equilibrate the ampule for approximately 30 minutes at room (ambient) temperature.

Procedure

STEP	ACTION
1	Access the i-STAT Cartridge Control option under Quality Tests in the Administration Menu. Enter the required information. The analyzer allows 15 minutes (or the customized timeout) to insert the cartridge after the last data entry.
2	Immediately before use, shake the ampule vigorously for 5 to 10 seconds to equilibrate the liquid and gas phases.
	To shake, hold the ampule at the tip and bottom with forefinger and thumb to minimize increasing the temperature of the solution. If necessary, tap the tip of the ampule to send solution back into the bottom section of the ampule.
3	Protect fingers with gauze, tissue or glove, or use an ampule breaker to snap off the tip of the ampule at the neck.
4	Immediately transfer the solution from the ampule into a capillary tube or syringe, and then immediately transfer the solution into a cartridge.
5	Immediately seal the cartridge and insert it into an analyzer – it is important not to expose the solution to room air since this will alter the results. **Note**: Since aqueous based solutions such as controls lack the buffering capabilities of whole blood, the transfer process from ampule to cartridge must be more expedient than with a patient sample.

Transfer with Capillary Tube	Plain capillary tubes are recommended to transfer an aqueous control from the ampule to the cartridge. When using a capillary tube (fresh capillary tubes with sufficient fill capacity are recommended), fill from the bottom of the ampule to avoid drawing air into the capillary tube. Avoid drawing solution from the surface by placing a finger over the far end of the tube as it is inserted into the ampule. Once the open end of the tube rests at the bottom of the ampule, uncover the other end to allow filling by capillary action.
Transfer with Syringe	Plain syringes are recommended to transfer an aqueous control from the ampule to the cartridge. When using a syringe (fresh 1cc or 3cc sterile syringe with 16 - 20 gauge needles are recommended), slowly draw approximately 1mL of solution from the bottom of the ampule.
	If air is trapped between the leading edge of the solution and the plunger, do not invert the syringe to expel it; this will not affect solution near the tip of the syringe.
	If air bubbles are continually drawn into the syringe, or if a bubble is trapped near the tip of the syringe, discard the ampule and syringe and use a fresh ampule and syringe.
	Expel one or two drops from the syringe before filling the cartridge.
Target Values	Target values (determined by testing multiple ampules of each level using multiple lots of cartridges and i-STAT analyzers that have passed the Electronic Simulator test) are printed on a value assignment sheet posted on the APOC website at www.pointofcare.abbott.
	Always be sure that the lot number printed on the insert matches the lot number on the label of the ampule in use, and that the software revision above the target value table matches the software revision in the analyzer.

Ranges

The ranges displayed represent the maximum deviation expected when controls and cartridges are performing properly.

Should results outside the ranges be obtained, refer to the Troubleshooting section that follows the Procedure for Testing Controls.

Target Values are specific to the i-STAT System. Results obtained from these aqueous controls with other methods may differ due to sample matrix effects.

Correction of PO_2 at Extreme Altitude

The partial pressure of oxygen in a solution will change as it equilibrates to the surrounding ambient pressure. The rate of change is faster in aqueous solutions than in whole blood due to the absence of red blood cells containing hemoglobin which binds oxygen molecules. This is of practical significance when testing aqueous solutions on blood gas analyzers as there will be a detectable shift in the partial pressure of oxygen in the sample as it equilibrates to the pressure in the flowpath of the analyzer.

The ranges for i-STAT aqueous control solutions are established for the degree of oxygen equilibration which occurs in the cartridges at or near sea level. PO_2 results for aqueous solutions, including i-STAT controls and Calibration Verification Set and proficiency (external quality control) samples, can be corrected for higher altitude environments using the following equations. Observed PO_2 values should be corrected before comparing them to the values in the value assignment sheet included with each box of i-STAT controls.

Equations:

For PO_2 values below 150 mmHg:
   PO_2 corrected = PO_2 observed + (0.067 x (760 – BP))
      Where BP is the barometric pressure reading from the Analyzer Status screen.
   (Approximate change: For every decrease of 15 mmHg in pressure from 760 mmHg, add 1 mmHg to observed value.)

For PO_2 value above 150 mmHg:
   PO_2 corrected = PO_2 observed + (0.029 x (760 – BP))
      Where BP is the barometric pressure reading from the Analyzer Status screen.
   (Approximate change: For every decrease of 35 mmHg in pressure from 760 mmHg, add 1 mmHg to observed value.)

CONTROLS FOR BLOOD GAS/ELECTROLYTE/METABOLITE CARTRIDGES (i-STAT TRICONTROLS)

Control Solutions

Aqueous-based control fluids are available for verifying the integrity of newly received cartridges. i-STAT TriControls Level 1, 2 and 3 are formulated at three clinically relevant levels with defined pH and hematocrit values and with known concentrations of:

Sodium	PCO$_2$	Glucose
Potassium	PO$_2$	Lactate
Chloride	TCO$_2$	BUN/Urea
Ionized Calcium		Creatinine

Each level of control is packaged in a box containing 10 individual 1.7 mL glass ampules.

The control solutions do not contain human serum or serum products, but do contain buffers and preservatives.

Reactive Ingredients for TriControls Materials

Analyte	Calibration Verification Level 1	Calibration Verification Level 2 and Control Level 1	Calibration Verification Level 3 and Control Level 2	Calibration Verification Level 4 and Control Level 3	Calibration Verification Level 5
Na (mmol/L)	97	118	124	150	159
K (mmol/L)	2.30	3.00	4.00	6.30	8.20
Cl (mmol/L)	67	76	94	119	134
Glu (mg/dL)	595	285	160	65	53
Urea (mg/dL)	114	44	8.4	4.6	3.0
iCa (mmol/L)	0.40	0.90	1.35	1.58	2.40
Lac (mmol/L)	17.7	8.30	3.00	1.63	1.52
Crea (mg/dL)	15.6	4.65	1.59	0.65	0.55
PCO$_2$ (mmHg)	96	65	40	26	12
PO$_2$ (mmHg)	40	63	120	163	500
H$^+$ (pH)	6.550	7.025	7.390	7.610	7.850

Storage

Refrigerated storage at 2-8 °C (35-46 °F) should be maintained until the printed expiration date on the box and ampule labels.

TriControls solutions may also be maintained at room temperature (18-30 °C; 64-86 °F) for up to 5 days.

Do not use TriControls solutions past the labeled expiration date on the box and ampule labels.

Best Results

For best results, ampules, cartridges and handhelds should be at the same temperature.

Ampule Use

When using cartridges that contain sensors for pH, PCO$_2$, PO$_2$ and ionized calcium, a separate ampule must be used for each cartridge being tested.

Do not use residual TriControls solution that may be in a syringe, ampule or capillary tube for additional testing of cartridges that contain sensors for ionized calcium, pH, PCO$_2$, or PO$_2$. However, cartridges without these sensors may be tested with remaining fluids if that testing is performed within 10 minutes of opening the ampule.

Before Use

i-STAT TriControls solutions require different temperature stabilization times depending on whether or not PO_2 is to be measured. If PO_2 is to be measured, equilibrate the ampule to room temperature for 4 hours prior to use. If PO_2 is not being measured, equilibrate the ampule for approximately 30 minutes at room temperature.

Procedure

STEP	ACTION
1	Access the Control option under Quality Tests in the Administration Menu. Enter the required information. The handheld allows 15 minutes (or the customized timeout) to insert the cartridge after the last data entry.
2	Immediately before use, shake the ampule vigorously for 5 to 10 seconds to equilibrate the liquid and gas phases. To shake, hold the ampule at the tip and bottom with forefinger and thumb to minimize increasing the temperature of the solution. If necessary, tap the tip of the ampule to send solution back into the bottom section of the ampule.
3	Protect fingers with gauze, tissue or glove, or use an ampule breaker to snap off the tip of the ampule at the neck.
4	Immediately transfer the solution from the ampule into a capillary tube or syringe, and then immediately transfer the solution into a cartridge.
5	Immediately seal the cartridge and insert it into a handheld – it is important not to expose the solution to room air since this will alter the results. **Note:** Since aqueous based solutions such as control materials lack the buffering capability of whole blood, the transfer process from ampule to cartridge must be more expedient than with a patient sample.

Transfer with Capillary Tube

Plain capillary tubes are recommended to transfer an aqueous control solution from the ampule to the cartridge. When using a capillary tube (fresh capillary tubes with sufficient fill capacity are recommended), fill from the bottom of the ampule to avoid drawing air into the capillary tube. Avoid drawing solution from the surface by placing a finger over the far end of the tube as it is inserted into the ampule. Once the open end of the tube rests at the bottom of the ampule, uncover the other end to allow filling by capillary action.

Transfer with Syringe

Plain syringes (fresh 1 cc or 3 cc sterile syringe with 16 – 20 gauge needles) are recommended to transfer aqueous control solutions from the ampule to the cartridge. When using a syringe, slowly draw approximately 1 mL of solution from the bottom of the ampule.

If air is trapped between the leading edge of the solution and the plunger, do not invert the syringe to expel it; this will not affect solution near the tip of the syringe.

If air bubbles are continually drawn into the syringe, or if a bubble is trapped near the tip of the syringe, discard the ampule and syringe and use a fresh ampule and syringe.

Expel one or two drops from the syringe before filling the cartridge.

Target Values

Target values (determined by testing multiple ampules of each level using multiple lots of cartridges and i-STAT handhelds that have passed the Electronic Simulator test) are printed on a Value Assignment Sheet posted on the APOC website at www.pointofcare.abbott.

Ensure that the lot number printed on the Value Assignment Sheet matches the lot number on the label of the ampule and that the software version above the target value table matches the software version in the handheld.

Ranges

The ranges displayed represent the maximum deviation expected when controls and cartridges are performing properly.

Should results outside these ranges be obtained, refer to the Troubleshooting section that follows the Procedure for Testing Controls in the System Manual.

Target Values are specific to the i-STAT System. Results obtained when testing these aqueous controls with other methods may differ due to matrix effects.

Correction of PO_2 at Extreme Altitude

The partial pressure of oxygen in a solution will change as it equilibrates to the surrounding ambient pressure. The rate of change is faster in aqueous solutions than in whole blood due to the absence of hemoglobin which binds oxygen. This is of practical significance when testing aqueous solutions on blood gas analyzers as there will be a detectable shift in the partial pressure of oxygen in the sample as it equilibrates to the pressure in the flowpath of the analyzer.

The ranges for i-STAT aqueous control solutions are established for the degree of oxygen equilibration that occurs in cartridges tested at or near sea level. PO_2 results for aqueous solutions, including i-STAT controls and Calibration Verification Set and proficiency (external quality control) samples, can be corrected for higher altitude environments using the following equations. Observed PO_2 values should be corrected before comparing them to the values on the Value Assignment Sheet posted on the APOC website at www.pointofcare.abbott.

Equations:

For PO_2 values below 150 mmHg:
    PO_2 corrected = PO_2 observed + (0.067 x (760 – BP))
        Where BP is the barometric pressure reading from the Analyzer Status screen.
    (Approximate change: For every decrease of 15 mmHg in pressure from 760 mmHg, add 1 mmHg to the observed value.)

For PO_2 values above 150 mmHg:
    PO_2 corrected = PO_2 observed + (0.029 x (760 – BP))
        Where BP is the barometric pressure reading from the Analyzer Status screen.
    (Approximate change: For every decrease of 35 mmHg in pressure from 760 mmHg, add 1 mmHg to the observed value.)

PRECISION

The additive used in the aqueous-based TriControls to simulate the effect of hematocrit in blood samples results in reduced precision in repeat measurement of electrolytes relative to the precision obtained when assaying with either standard control/calibration verification materials or whole blood. The imprecision is related to the concentration of additive. The increase is pronounced at higher levels of indicated hematocrit.

Internal testing of non-Abbott aqueous control materials on the i-STAT System which have hematocrit, blood gas and chemistry functionalities exhibit similar precision to that observed for TriControls.

The acceptance limits which have been established for these control solutions are wider than analogous limits established for the current i-STAT control and calibration verification solutions, reflecting the precision effect highlighted above.

The situation where better precision will be obtained in clinical samples than in control solutions is not unusual. A similar effect is observed in control solutions for the i-STAT measurement of PO_2.

The precision data shown below, including results for TriControls solutions, were collected during studies at an Abbott Point of Care facility. SD and %CV are typical of performance; current Value Assignment Sheets should be referenced for applicable mean data. Refer to the value assignment sheets posted on the APOC website at www.pointofcare.abbott.

Analyte	Level 1			Level 3		
	Mean	SD	%CV	Mean	SD	%CV
Na (mmol/L)	120	0.46	0.4%	158	1.39	0.9%
K (mmol/L)	2.85	0.038	1.3%	6.15	0.058	0.9%
Cl (mmol/L)	72.9	0.63	0.9%	113.6	2.30	2.0%
Glu (mg/dL)	289	2.4	0.8%	41.8	0.68	1.6%
Urea (mg/dL)	69.7	0.94	1.3%	5.5	0.45	8.2%
iCa (mmol/L)	0.84	0.012	1.4%	1.51	0.030	2.0%
Lac (mmol/L)	6.35	0.08	1.3%	0.810	0.03	3.7%
Crea (mg/dL)	4.16	0.123	3.0%	0.50	0.046	9.1%
PCO_2 (mmHg)	63.8	1.57	2.5%	19.6	0.40	2.0%
PO_2 (mmHg)	65.1	3.12	4.8%	146.5	6.00	4.1%
H^+ (pH)	7.165	0.005	0.07%	7.674	0.003	0.04%
Hct (%)	17.6	0.40	2.3%	57.1	1.00	1.75%
TCO_2 (mmHg)	17.4	0.62	3.6%	30.4	0.70	2.3%

CONTROLS FOR ACT CARTRIDGES

Intended Use	The i-STAT® ACT Control Level 1 and ACT Control Level 2 are intended for use to verify the integrity of newly received i-STAT ACT cartridges. The controls produce clotting times expected for moderate and high level heparinization to indicate that the cartridges are functioning properly.
Contents	Each level of control is packaged as a box of 5 vials of lyophilized human plasma and 5 vials of 9.5 ± 1.5 mmol/L calcium chloride diluent.
Storage	i-STAT ACT controls, Levels 1 and 2, are contained in 6 mL vials. Separate 6 mL vials contain 1-3 mL of calcium chloride solution for reconstitution. Refrigerated storage at 2 to 8 °C (35 to 46 °F) should be maintained until the printed expiration date on the box and vial labels. Do not use beyond the expiration date on the box and vial labels.
	Control solutions may also be stored at room temperature for up to 4 hours (18 to 30 °C or 64 to 86 °F). If left out longer than 4 hours at room temperature, they should be discarded.

Warnings and Precautions	Handle this product using the same safety precautions used when handling any potentially infectious material. The human plasma used in the preparation of this product has been tested by FDA approved test methods and found negative/non-reactive for HIV-1, HIV-2, HBsAg, and HCV. However, no known test method can offer complete assurance that products derived from human blood will not transmit infectious disease.

Dispose of this product as biohazardous waste according to all local, state, and national regulations.

Directions for Use	Prior to testing, vials containing the lyophilized plasma and CaCl$_2$ reconstituting fluid should stand at room temperature (18 - 30 ºC or 64 - 86 ºF) for a minimum of 45 minutes. For best results, vials, cartridges, and analyzers should be at the same temperature.

Reconstitute only one level of control plasma at a time. CONTROL SOLUTIONS MUST BE USED IMMEDIATELY (less than 30 seconds) AFTER COMPLETING THE RECONSTITUTION AND MIXING STEPS.

STEP	ACTION
1	After 45 minute room temperature equilibration, remove the cap and stopper from one lyophilized human plasma control vial and remove the cap from one vial of calcium chloride reconstituting fluid.
2	Pour the entire contents of the calcium chloride vial into the lyophilized human plasma control vial. Place the stopper back in the reconstituted control vial, sealing the vial appropriately so that the contents do not leak or spill out.
3	Allow the vial to sit at room temperature for 1 minute.
4	Mix the contents of the vial by swirling gently for 1 minute, then inverting slowly for 30 seconds.

Note: To minimize foaming of the control sample, avoid vigorous or rapid mixing motion. Visually inspect the control vial to ensure that the sample is fully reconstituted. If not, discard the reconstituted fluid and start over with fresh vials. |
| 5 | Using a plastic transfer pipette, plastic syringe, or plastic capillary tube with no anticoagulant, immediately transfer the solution from the vial into the ACT cartridge |
| 6 | Immediately seal the cartridge and insert it into an analyzer.

Note: Additional ACT cartridges may be tested with the remaining fluid if used within 30 seconds of complete reconstitution of the sample. |

Control Target Values and Expected Ranges	Target values (determined by testing multiple vials of each level using multiple lots of i-STAT cartridges with analyzers that have passed the Electronic Simulator test) are printed on a value assignment sheet posted on the APOC website at www.pointofcare.abbott. The ranges displayed represent the maximum deviation expected when controls and cartridges are performing properly. Should results outside the range be obtained, refer to the Troubleshooting portion of this section of the i-STAT System Manual. Always be sure that the lot number printed on the value assignment sheet matches the lot number on the label of the vial in use, and that the software revision above the table matches the software revision in the analyzer (check the status page on the analyzer).

Note: Target values are specific to the i-STAT System; results obtained from these reconstituted control plasmas may differ if used with other methods.

CONTROLS FOR PT/INR CARTRIDGES

Intended Use
The i-STAT® PT Control Level 1 (normal) and PT Control Level 2 (abnormal) are used to verify the integrity of newly received PT/INR cartridges.

Contents
Each level of control is packaged as a box of 5 vials of lyophilized human plasma and 5 vials of 9.5 ± 1.5 mmol/L calcium chloride diluent.

Storage
i-STAT PT controls, Levels 1 and 2, are contained in 6 mL vials. Separate 6 mL vials contain 1-3 mL of calcium chloride solution for reconstitution. Refrigerated storage at 2 to 8 °C (35 to 46 °F) should be maintained until the printed expiration date on the box and vial labels. Do not use beyond the expiration date on the box and vial labels.

Control solutions may also be stored at room temperature for up to 4 hours (18 to 30 °C or 64 to 86 °F). If left out longer than 4 hours at room temperature, they should be discarded.

Warnings and Precautions
Handle this product using the same safety precautions used when handling any potentially infectious material. The human plasma used in the preparation of this product has been tested by FDA approved test methods and found negative/non-reactive for HIV-1, HIV-2, HBsAg, and HCV. However, no known test method can offer complete assurance that products derived from human blood will not transmit infectious disease.

Dispose of this product as biohazardous waste according to all local, state, and national regulations.

Directions for Use
Prior to testing, vials containing the lyophilized plasma and $CaCl_2$ reconstituting fluid should stand at room temperature 18-30 °C (64-86 °F) for a minimum of 45 minutes. For best results, vials, cartridges, and analyzers should be at the same temperature.

Reconstitute only one level of control plasma at a time. CONTROL SOLUTIONS MUST BE USED IMMEDIATELY (less than 30 seconds) AFTER COMPLETING THE RECONSTITUTION AND MIXING STEPS.

STEP	ACTION
1	After 45 minute room temperature equilibration, remove the cap and stopper from one lyophilized human plasma control vial and remove the cap from one vial of calcium chloride reconstituting fluid.
2	Pour the entire contents of the calcium chloride vial into the lyophilized human plasma control vial. Place the stopper back in the reconstituted control vial, sealing the vial appropriately so that the contents do not leak or spill out.
3	Allow the vial to sit at room temperature for 1 minute.
4	Mix the contents of the vial by swirling gently for 1 minute, then inverting slowly for 30 seconds. **Note:** To minimize foaming of the control sample, avoid vigorous or rapid mixing motion. Visually inspect the control vial to ensure that the sample is fully reconstituted. If not, discard and start over with fresh vials.
5	Using a plastic transfer pipette, plastic syringe, or plastic capillary tube with no anticoagulant, immediately transfer the solution from the vial into the PT/INR cartridge.
6	Immediately seal the cartridge and insert it into an analyzer. **Note:** Additional PT/INR cartridges may be tested with the remaining fluid if used within 30 seconds of complete reconstitution of the sample.

Control Target Values and Expected Ranges	Target values (determined by testing multiple vials of each level using multiple lots of i-STAT cartridges with analyzers that have passed the Electronic Simulator test) are printed on a value assignment sheet posted on the APOC website at www.pointofcare.abbott. The ranges displayed represent the maximum deviation expected when controls and cartridges are performing properly. Should results outside the range be obtained, refer to the Troubleshooting portion of this section of the i-STAT System Manual. Always be sure that the lot number printed on the value assignment sheet matches the lot number on the label of the vial in use, and that the software revision above the table matches the software revision in the analyzer (check the status page on the analyzer).

Note: Target values are specific to the i-STAT System; results obtained from these reconstituted control plasmas may differ if used with other methods.

CONTROLS FOR i-STAT cTnI, BNP, AND CK-MB CARTRIDGES

Intended Use:

i-STAT cTnI, BNP, and CK-MB Control Levels 1, 2, and 3 are intended for use as an assayed quality control material which can be used to verify the integrity of newly received i-STAT cTnI, BNP, and CK-MB cartridges.

Notes:
- These controls do not contain sodium azide as a preservative.
- These controls do not require freezing.

Warnings and Precautions

Each plasma donor unit used in the manufacture of this product has been tested by FDA accepted methods and found negative/non-reactive for the presence of HBsAg and the antibody to HIV-1/2, HCV, HIV NAT, and HIV-1 Ag. While these test methods are highly accurate, they do not guarantee that all infected units will be detected. Because no known test method can offer complete assurance the hepatitis B virus, hepatitis C virus, human immunodeficiency virus (HIV) or other infectious agents are absent, all products containing human source material should be considered potentially infectious and handled with the same precautions used with patient specimens.

Bacterial contamination of the control can cause an increase in turbidity. Do not use the control material if there is visible evidence of microbial growth or gross contamination.

Storage and Stability

Control material is a ready-to-use liquid control requiring no reconstitution or frozen storage. The controls are stable until the expiration date on the vial label when stored unopened at 2-8 °C (35-46 °F). Once opened, these controls are stable for 30 days when stored tightly capped at 2-8 °C (35-46 °F).

Procedure

1. Access the Control option under Quality Tests in the Administration Menu. Enter the required information. The handheld allows 15 minutes (or the customized timeout period) to insert the cartridge after the last data entry.

2. Immediately before use, gently mix the contents of the control vial to ensure homogeneity. Avoid foaming of the sample.

3. Open the vial and transfer a drop of the fluid into the i-STAT cartridge using the dropper tip, a plain capillary tube, plain syringe, or plastic transfer pipette. Tightly recap the control vial and store it at 2-8 °C (35-46 °F).

4. Seal the cartridge and immediately insert it into the i-STAT 1 handheld.

Control Target Values and Ranges

See Value Assignment Sheets posted on the APOC website at www.pointofcare.abbott. The Value Assignment Sheet displays target values and ranges expected when cartridges, controls, and equipment are performing properly.

Always ensure that the lot number and software revision on the Value Assignment Sheet match the lot number of the vial in use and the software revision in the handheld.

Target values are specific to the i-STAT System. Results may differ if used with other methods.

See Troubleshooting section below for procedures to follow if control results are out of range.

PERFORMING ELECTRONIC SIMULATOR TEST

Procedure for Internal Electronic Simulator

The internal Electronic Simulator test cycle is automatically activated when a cartridge is inserted after the customized interval is reached. If the analyzer passes the simulator test, the cartridge test cycle proceeds. If not, the analyzer displays "ELECTRONIC SIMULATOR FAIL." If the analyzer is customized to block testing when it fails the simulator test, the same cartridge can be re-inserted immediately after the FAIL message is displayed. If the analyzer fails the simulator test again, see the Troubleshooting section that follows the Procedure. If less than three minutes has elapsed, the cartridge can be inserted into another analyzer. If the analyzer is not customized to block testing after a failed simulator test, the internal simulator test will not repeat until the programmed interval has elapsed.

PROCEDURE FOR EXTERNAL ELECTRONIC SIMULATOR

```
   ID: 20825
09:10 22JUN00

 ELECTRONIC
 SIMULATOR

 FAIL     L
```

Display	Step	Analyzer Response / Comments
	Press the **On/Off** key to turn the analyzer on.	Logo briefly displayed followed by Test Menu.
Test Menu	Press the **Menu** key.	
Administration Menu	Press **3** to select Quality Tests.	
Quality Tests Menu	Press **4** to select Simulator.	
Scan or Enter Operator ID	Press **Scan** to scan the Operator ID or manually enter the Operator ID and press **Enter**.	If enabled, the analyzer will validate ID and/or ask for the ID to be repeated.
Scan or Enter Simulator ID	Press **Scan** to scan the Simulator ID or manually enter the Simulator ID and press **Enter**.	The simulator serial number can be used as an ID. If the simulator does not have a barcode, one can be made on-site and affixed to the simulator (not near contact pads).
INSERT SIMULATOR	Remove the cover protecting the contact pads and insert the simulator straight into the analyzer. Avoid touching the contact pads.	Inserting the simulator at an angle may cause a Quality Check message to be displayed.
Contacting Simulator Please wait… Time to Results bar Simulator Locked	Do not attempt to remove the simulator until the results are displayed and the "Simulator Locked" message is removed.	
Result screen: ID of Simulator Date and Time ELECTRONIC SIMULATOR PASS or FAIL 1 - Test Options	Test Options Simulator 1 - Next Simulator 2 - Same Simulator 3 - History	If **PASS** is displayed, continue to use the analyzer. Remove the simulator and return it to its protective case. If **FAIL** is displayed, see the Troubleshooting in this section of the manual.

| Caution | The analyzer will continue to initialize test cycles when the analyzer is customized to warn, but not block testing when a scheduled external Electronic Simulator test is missed, when a FAIL result for the external Electronic Simulator test is ignored, and when the analyzer fails the internal Electronic Simulator test and the lockout feature is not enabled. |

TROUBLESHOOTING FAILED ELECTRONIC SIMULATOR TEST

| Introduction | With both the internal and external Electronic Simulator, an analyzer may occasionally fail a simulator test even though it is in proper operating condition due to the extremely sensitive nature of the test. |

| External Simulator | Run the test again or try another simulator, as it is possible that the test will pass on a second try. The test can also fail if the external Electronic Simulator is malfunctioning such as after being dropped. |

Occasionally when an analyzer is moved from a cold environment to a warm, humid environment, moisture may condense on the internal connector. An analyzer in this condition will fail the electronic test and the failure code "L" will be displayed. Allow the analyzer to sit for half an hour to allow the moisture to evaporate, then insert the Electronic Simulator again. If the analyzer passes the second electronic test, continue using it. If the analyzer fails the second time, record the letter or Quality Check Code displayed with the FAIL message and refer to Support Services information in the Troubleshooting section.

| Internal Simulator | The cartridge or an external Electronic Simulator should be rerun to confirm the failure. The analyzer's connector pins are in contact with the biosensor chips in the cartridge being tested when the internal Electronic Simulator test is being performed. The test can fail if the contact pads have been contaminated in some way. |

Lockout Enabled: Rerun the cartridge in the same analyzer to ensure the FAIL was not due to a one-time spike of electrical noise. If the test fails again, rerun the cartridge in another analyzer if immediately available. Note that the cartridge should not be run if there is more than a three minute delay from the time it is filled. If the cartridge fails in more than one analyzer, use another cartridge. When Lockout is enabled, the analyzer will continue to perform the internal Electronic Simulator test each time a cartridge is inserted until the test (internal or external) passes.

Lockout Not Enabled: Rerun the cartridge in another analyzer if immediately available. Note that the cartridge should not be run if there is more than a three minute delay from the time it is filled. When Lockout is not enabled, the analyzer will run the next cartridge without performing the internal Electronic Simulator test until the specified time has elapsed. Verify the analyzer using an external Electronic Simulator.

CHECKING THE THERMAL PROBES IN THE i-STAT ANALYZER

Verification for Handheld Analyzers

Verify the thermal probe check for the i-STAT 1 Analyzer as follows:

- External Electronic Simulator used routinely and results transmitted to a Central Data Station Version 5: On the CDS, click on **Data Viewer**, then on **Simulator**. Look under the Probe Delta column. Check that there is a value from -0.1 to +0.1 inclusive listed for each analyzer in use in the last 30 days. A value of "--.--" indicates that the conditions to complete the thermal probe check were not met. Use the procedure below to check any analyzer that does not have a numeric value listed.

- External Electronic Simulator used routinely, results not transmitted to a Central Data Station: Use the procedure below to check the thermal probes on each analyzer every six months.

- Internal Electronic Simulator used routinely: Use the procedure below to check the thermal probes on each analyzer twice a year.

Procedure for Handheld Analyzers

Check the thermal probes on the i-STAT 1 Analyzer as follows:

1. If the analyzer and simulator have been stored separately in areas where the ambient temperature differs by more than 3 °C (5 °F), allow the simulator and analyzer to stand in the same place, out of drafts, for 30 minutes before inserting the simulator into the analyzer. Handle the simulator as little as possible to maintain its thermal uniformity and stability.

2. Insert the simulator into the analyzer.

3. When results are displayed, the difference between the thermal probes can be viewed on the analyzer's screen:

   - Press the **period** key.

4. Interpretation of the thermal probe check value:

   - Acceptable: a value from -0.1 to +0.1 inclusive.

   - Not acceptable: a FAIL message with a "t" Quality Check Code or a value greater than 0.1. Repeat the procedure to confirm results. Contact your Technical Support representative if the repeat thermal check value is greater than 0.1 or less than -0.1.

   - Repeat the procedure: if "--.--" is displayed. Take care to handle the simulator a little as possible. It may help to partially insert the simulator into the analyzer and let it stand for 15 minutes before inserting all the way.

Documentation of Results

The results of the thermal probe check are stored in the Central Data Station. If the Central Data Station is not available, use the form included in this section of the Manual to record the results.

PERFORMING CONTROL TEST ON CARTRIDGE

Procedure for Testing Controls

Initiating control tests from the Quality Test Menu allows results to be stored in separate categories for the purpose of documentation and review.

- DO NOT insert cartridge to start test.

- DO NOT open cartridge pouch before scanning the barcode.

- If Quality Check Code 69 or 140 appears, see Analyzer Coded Messages Technical Bulletin for Troubleshooting Information.

1. Press ⏻ to turn on handheld.

2. Press (MENU) → (3) → (1) for Control Samples.

3. Follow handheld prompts.

4. Scan the lot number on the cartridge pouch.

   - Position barcode 3 - 9 inches from scanner window on the handheld.

   - Press and hold (SCAN) to activate the scanner.

   - Align the red laser light so it covers the entire barcode.

   - The handheld will beep when it reads the barcode successfully.

5. Continue normal procedures for preparing the sample, filling and sealing the cartridge.

6. Push the sealed cartridge into the handheld port until it clicks into place. Wait for the test to complete.

   Note: For ACT, PT/INR, Hct, and immunoassay testing, the handheld must remain on a level surface with the display facing up during testing.

7. Review results.
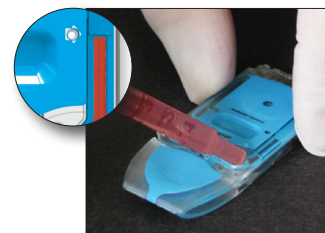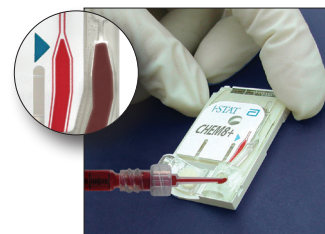
TROUBLESHOOTING OUT-OF-RANGE CONTROL RESULTS ON CARTRIDGE

Troubleshooting

Verify that the following conditions are met and then repeat the test:

- The correct expected values insert is being used and the correct cartridge type and lot number listing is being used.
- Expiration date printed on cartridge pouch and control ampule or vial have not been exceeded.
- Room temperature expiration date for cartridge and control have not been exceeded.
- Cartridge and control have been stored correctly.
- The control has been handled correctly: See the directions for use.
- The analyzer being used passes the Electronic Simulator test.

If the results are still out of range despite meeting the above criteria, repeat the test using a new box of control solutions and/or cartridges. If the results are still out of range, refer to Support Services information in the Technical Bulletins section.

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i-STAT System Incoming Cartridge QC Log

Cartridge Type: _____ **Lot No.:** _____ **Exp. Date:** _____ **Rec'd Date:** _____ **Quant:** _____ **Temp. Strip:** _____

Control Name: _____ **Lot No.:** _____ **Exp. Date:** _____ **Level:** _____

TEST	TEST	TEST	TEST	TEST	TEST	TEST	TEST
RANGE	RANGE	RANGE	RANGE	RANGE	RANGE	RANGE	RANGE

Control Name: _____ **Lot No.:** _____ **Exp. Date:** _____ **Level:** _____

TEST	TEST	TEST	TEST	TEST	TEST	TEST	TEST
RANGE	RANGE	RANGE	RANGE	RANGE	RANGE	RANGE	RANGE

Control Name: _____ **Lot No.:** _____ **Exp. Date:** _____ **Level:** _____

TEST	TEST	TEST	TEST	TEST	TEST	TEST	TEST
RANGE	RANGE	RANGE	RANGE	RANGE	RANGE	RANGE	RANGE

Control Name: _____ **Lot No.:** _____ **Exp. Date:** _____ **Level:** _____

TEST	TEST	TEST	TEST	TEST	TEST	TEST	TEST
RANGE	RANGE	RANGE	RANGE	RANGE	RANGE	RANGE	RANGE

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i-STAT System QC Log: Expiration Date and Storage Conditions

DATE	LOCATION	CARTRIDGE TYPE	LOT #	REFRIGERATED 2 TO 8° C (35 TO 46° F)			ROOM TEMPERATURE 18 TO 30° C (64 TO 86° F)			ACTIONS	INSP.
				QTY	EXP. DATE	TEMP	QTY	EXP. DATE	TEMP		

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i-STAT Cartridge Quality Control Action Log

DATE	TIME	CONTROL LEVEL	CONTROL LOT	CARTRIDGE LOT	PROBLEM	CORRECTIVE ACTION	OPERATOR

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i-STAT Electronic Simulator Log for Analyzer Serial Number: _____   Year: _____

DATE	TIME	PASS FAIL	SIMULATOR ID	OPERATOR	TIME	PASS FAIL	SIMULATOR ID	OPERATOR	TIME	PASS FAIL	SIMULATOR ID	OPERATOR

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i-STAT Electronic Simulator Action Log

DATE	TIME	ANALYZER	FAILURE CODE OR LETTER	SIMULATOR ID	ACTION	OPERATOR

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i-STAT Analyzer Thermal Probe Check

Year: _____

Analyzer Serial No.: _____

DATE	SIMULATOR SERIAL NO.	THERMAL PROBE DELTA RESULT Acceptable Range: -0.1 TO +0.1	COMMENTS	OPERATOR

Analyzer Serial No.: _____

DATE	SIMULATOR SERIAL NO.	THERMAL PROBE DELTA RESULT Acceptable Range: -0.1 TO +0.1	COMMENTS	OPERATOR

Analyzer Serial No.: _____

DATE	SIMULATOR SERIAL NO.	THERMAL PROBE DELTA RESULT Acceptable Range: -0.1 TO +0.1	COMMENTS	OPERATOR

Analyzer Serial No.: _____

DATE	SIMULATOR SERIAL NO.	THERMAL PROBE DELTA RESULT Acceptable Range: -0.1 TO +0.1	COMMENTS	OPERATOR

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i-STAT®
TECHNICAL BULLETIN

i-STAT Total β-hCG Controls and Calibration Verification Material

INTENDED USE

The i-STAT® Total β-hCG Controls are used to monitor performance of the i-STAT Total β-hCG test.

The i-STAT Total β-hCG Calibration Verification materials are used to verify the calibration of the i-STAT Total β-hCG test throughout the reportable range.

PRODUCT DESCRIPTION

6 Bottles, (1 mL each) of i-STAT Control fluid prepared in human serum.

6 Bottles, (1 mL each) of i-STAT Calibration Verification material prepared in human serum.

Note: These controls and calibration verification materials do not contain sodium azide as a preservative.

Warnings and Precautions

Handle the products using the same safety precautions used when handling any potentially infectious material. The human serum used in the preparation of these products has been tested by FDA approved test methods and found negative/non-reactive for HBsAg, anti-HIV 1 /2, anti-HCV, and HIV 1 Ag. However, no known test method can offer complete assurance that products derived from human blood will not transmit infectious disease.

Do not use Control or Calibration Verification material if they are received uncapped.

Bacterial contamination of the Control or Calibration Verification material can cause an increase in turbidity. Do not use the materials if there is visible evidence of microbial growth or gross contamination.

Storage and Stability

i-STAT Total β-hCG Control and Calibration Verification materials are ready-to-use liquid controls requiring no reconstitution or frozen storage. They are stable until the expiration date on the vial label when stored unopened at 2-8 °C. Once opened, i-STAT Total β-hCG Control and Calibration Verificaton fluids are stable for 30 days when stored tightly capped at 2-8 °C.

Abbott
Point of Care

PROCEDURE

1. Access the Control or Cal Ver option under Quality Tests in the Administration Menu, as applicable. Enter the required information. The handheld allows 15 minutes (or the customized timeout period) to insert the cartridge after the last data entry.

2. Immediately before use, gently mix the contents of the control vial to ensure homogeneity. Avoid foaming of the sample.

3. Open the vial and transfer a drop of fluid into the i-STAT Total β-hCG cartridge using the vial dropper tip. Tightly recap the control vial and store it at 2-8 °C.

4. Seal the cartridge and immediately insert into the handheld.

TARGET VALUES AND RANGES

Target values (determined by testing multiple vials of each level using multiple lots of cartridges and i-STAT 1 Analyzers that pass the Electronic Simulator test) are printed on a Value Assignment Sheet posted on the APOC website at www.abbottpointofcare.com. The Value Assignment Sheet displays target values and ranges expected when Controls, Calibration Verification materials and equipment are performing properly. Should results fall outside the range, refer to the Quality Control section of the i-STAT 1 System Manual.

Always ensure that the control or calibration verification material lot number and software revision on the Value Assignment Sheet matches the lot number of the vial in use and the software version in the handheld.

Target values are specific to the i-STAT System. The values assigned to the Controls and Calibration Verification material are traceable to WHO 5th International Standard for Chorionic Gonadotropin (NIBSC Code 07/364). Results may differ if used with other methods.

Analyze the control material in the Control pathway, and Calibration Verification material in the Cal Ver pathway under the Quality Tests option of the i-STAT 1 Analyzer Administration menu.

i-STAT is a registered trademark of the Abbott Group of Companies in various jurisdictions.

IVD

Rx Only

NOTE: CALIBRATION VERIFICATION MATERIALS SHIPPED WITH GEL PACKS WILL INCLUDE A FOUR-WINDOW INDICATOR TO MONITOR AND VERIFY TEMPERATURE DURING TRANSIT.

CALIBRATION VERIFICATION FOR BLOOD GAS/ELECTROLYTE/METABOLITE CARTRIDGES

Purpose

Calibration Verification is a procedure intended to verify the accuracy of results over the entire measurement range of a test. The performance of this procedure at defined intervals may be required by regulatory or accreditation bodies. While the Calibration Verification Set contains five levels, verification of the measurement range could be accomplished using the lowest, highest and mid levels.

Overview of Procedure

APOC recommends that each sensor type be included in the Calibration Verification procedure using a selection of analyzers that have passed the Electronic Simulator check. See the Technical Bulletin "Calibration Verfication and the i-STAT System" for more information.

Calibration Verification Solutions for Cartridges

A five-level Calibration Verification Set is available to verify the calibration of i-STAT cartridges throughout the reportable ranges for:

Sodium	pH	Glucose
Potassium	PCO_2	Lactate
Chloride	PO_2	BUN/Urea
Ionized Calcium	TCO_2	Creatinine

There are four 1.7 mL glass ampules of each level in the set.

Reactive Ingredients

See the table on page 14-3 of the Quality Control section for full information.

Storage

Refrigerated storage at 2 to 8 °C (35 to 46 °F) should be maintained until the printed expiration date on the box and ampule labels. Calibration Verification fluids may also be stored at room temperature for up to 5 days (18 to 30 °C or 64 to 86 °F). Prolonged storage at temperatures greater than 30 °C (86 °F) may cause changes in the values of some analytes. Do not use beyond the expiration date on the box and ampule labels.

If stored refrigerated, the calibration verification material should be equilibrated to room temperature for at least four (4) hours prior to testing.

Ampule Use

When using cartridges that contain sensors for pH, PCO_2, PO_2 and ionized calcium, a separate ampule must be used for each cartridge being tested. If these sensors are not present, the contents of one ampule may be used to fill more than one cartridge as long as the cartridges are filled and inserted into an analyzer within 10 minutes of opening the ampule.

Best Results

For best results, ampules, cartridges and analyzers should be at the same temperature.

i-STAT CALIBRATION VERIFICATION SET

Before Use

i-STAT Calibration Verification solutions require different temperature stabilization times depending on whether or not oxygen is to be measured.   If oxygen is to be measured, equilibrate the ampule to room (ambient) temperature for 4 hours. If not, equilibrate the ampule to room (ambient) temperature for 30 minutes.

Procedure

STEP	ACTION
1	Immediately before use, shake the ampule vigorously for 5 to 10 seconds to equilibrate the liquid and gas phases. To shake, hold the ampule at the tip and bottom with forefinger and thumb to minimize increasing the temperature of the solution. If necessary, tap the tip of the ampule to send solution back into the bottom section of the ampule.
2	Protect fingers with gauze, tissue or glove, or use an ampule breaker to snap off the tip of the ampule at the neck.
3	Immediately transfer the solution from the ampule into a plain capillary tube or plain syringe, and then immediately transfer the solution into a cartridge.
4	Immediately seal the cartridge and insert it into an analyzer – it is important not to expose the solution to room air since this will alter the results.

Note: Since aqueous based solutions such as controls lack the buffering capabilities of whole blood, the transfer process from ampule to cartridge must be more expedient than with a patient sample.

Transfer with Capillary Tube

Plain capillary tubes are recommended to transfer aqueous calibration verification material from the ampule to the cartridge. When using a capillary tube (fresh capillary tubes with sufficient fill capacity are recommended), fill from the bottom of the ampule.

Avoid drawing solution from the surface by placing a finger over the far end of the tube as it is inserted into the ampule.

Once the open end of the tube rests at the bottom of the ampule, uncover the other end to allow filling by capillary action.

Transfer with Syringe

Plain syringes are recommended to transfer aqueous calibration verification material from the ampule to the cartridge. When using a syringe (fresh 1 mL or 3 mL sterile syringes with 16 - 20 gauge needles are recommended), slowly draw approximately 1 mL of solution from the bottom of the ampule.

If air is trapped between the leading edge of the solution and the plunger, do not invert the syringe to expel it; this will not affect solution near the front of the syringe.

If air bubbles are continually drawn into the syringe, or if a bubble is trapped near the tip of the syringe, discard the ampule and syringe and use a fresh ampule and syringe.

Expel one or two drops from the syringe before filling the cartridge.

Acceptable Criteria	Target values (determined by testing multiple ampules of each level using multiple lots of i-STAT cartridges with analyzers that have passed the Electronic Simulator test) are printed on a Value Assignment Sheet posted on the APOC website at www.pointofcare.abbott.

Calibration throughout the reportable range of each analyte is verified if each analyte value falls within the corresponding range in the Value Assignment Sheet.

If the result for a level is outside the range published in the Value Assignment Sheet, two additional cartridge runs should be performed on this level and the three results averaged and then compared to the Value Assignment Sheet range. If this average value is still outside the acceptable range, troubleshooting may be required.

Note: If the Calibration Verification Set is to be used to assess linearity, plot the analyte value against the mean value of the acceptable range. The concentrations of analytes in the Calibration Verification Set are not intended or prepared to be equally spaced.

If testing at extreme altitude refer to Correction of PO_2 at Extreme Altitude under Controls for Blood Gas/Electrolyte/Metabolite Cartridges in the Quality Control section of the manual.

i-STAT CHEM8+ CALIBRATION VERIFICATION LEVEL 1B

Overview of Procedure

i-STAT recommends that each sensor type be included in the Calibration Verification procedure using a selection of analyzers that have passed the Electronic Simulator check. See the Technical Bulletin "Calibration Verfication and the i-STAT System" for more information.

Calibration Verification Solution for CHEM8+ Cartridges

i-STAT CHEM8+ Calibration Verification Level 1b is available for purchase to verify the calibration of the i-STAT CHEM8+ TCO_2 at the low end of the reportable range.

There are ten 1.7 mL glass ampules in each box.

Note: For testing all CHEM8+ cartridge analytes, use either the i-STAT TriControls Calibration Verification Set (includes hematocrit) or the i-STAT Calibration Verification Set (does not include hematocrit).

Storage

Refrigerated storage at 2 to 8 °C (35 to 46 °F) should be maintained until the printed expiration date on the box and ampule labels. i-STAT CHEM8+ Calibration Verification fluids may also be stored at room temperature for up to 5 days (18 to 30 °C or 64 to 86 °F). Prolonged storage at temperatures greater than 30 °C (86 °F) may cause changes in the values of some analytes. Do not use beyond the expiration date on the box and ampule labels.

Ampule Use

A separate ampule must be used for each cartridge being tested.

Best Results

For best results, ampules, cartridges and analyzers should be at the same temperature.

Before Use

Equilibrate the ampule to room (ambient) temperature for 30 minutes.

Procedure	STEP	ACTION
	1	Immediately before use, shake the ampule vigorously for 5 to 10 seconds to equilibrate the liquid and gas phases. To shake, hold the ampule at the tip and bottom with forefinger and thumb to minimize increasing the temperature of the solution. If necessary, tap the tip of the ampule to send solution back into the bottom section of the ampule.
	2	Protect fingers with gauze, tissue or glove, or use an ampule breaker to snap off the tip of the ampule at the neck.
	3	Immediately transfer the solution from the ampule into a plain capillary tube or plain syringe, and then immediately transfer the solution into a cartridge.
	4	Immediately seal the cartridge and insert it into an analyzer – it is important not to expose the solution to room air since this will alter the results.

Note: Since aqueous based solutions such as controls lack the buffering capabilities of whole blood, the transfer process from ampule to cartridge must be more expedient than with a patient sample.

Transfer with Capillary Tube

Plain capillary tubes are recommended to transfer aqueous calibration verification material from the ampule to the cartridge. When using a capillary tube (fresh capillary tubes with sufficient fill capacity are recommended), fill from the bottom of the ampule.

Avoid drawing solution from the surface by placing a finger over the far end of the tube as it is inserted into the ampule.

Once the open end of the tube rests at the bottom of the ampule, uncover the other end to allow filling by capillary action.

Transfer with Syringe

Plain syringes are recommended to transfer aqueous calibration verification material from the ampule to the cartridge. When using a syringe (fresh 1 mL or 3 mL sterile syringes with 16 - 20 gauge needles are recommended), slowly draw approximately 1mL of solution from the bottom of the ampule.

If air is trapped between the leading edge of the solution and the plunger, do not invert the syringe to expel it; this will not affect solution near the front of the syringe.

If air bubbles are continually drawn into the syringe, or if a bubble is trapped near the tip of the syringe, discard the ampule and syringe and use a fresh ampule and syringe.

Expel one or two drops from the syringe before filling the cartridge.

Acceptable Criteria

Target values (determined by testing multiple ampules of each level using multiple lots of i-STAT cartridges with analyzers that have passed the Electronic Simulator test) are printed on a Value Assignment Sheet posted on the APOC website at www.pointofcare.abbott.

If the result is outside the range published in the Value Assignment Sheet, two additional cartridge runs should be performed on this level and the three results averaged and then compared to the Value Assignment Sheet range. If this average value is still outside the acceptable range, troubleshooting may be required.

CALIBRATION VERIFICATION FOR BLOOD GAS/ ELECTROLYTE/ METABOLITE CARTRIDGES (i-STAT TRICONTROLS)

Purpose
Calibration Verification is a procedure intended to verify the accuracy of results over the entire measurement range of a test. The performance of this procedure at defined intervals may be required by regulatory accreditation bodies. While the Calibration Verification Set contains five levels, verification of the measurement range could be accomplished using the lowest, highest and mid levels.

Overview of Procedure
It is recommended that each sensor type be included in the Calibration Verification procedure using a selection of handhelds that have passed the Electronic Simulator check. See Technical Bulletin "Calibration Verification and the i-STAT System" for more information.

Calibration Verification Solutions for Cartridges
A five-level Calibration Verification Set is available to verify the calibration of i-STAT cartridges throughout the reportable ranges for:

Sodium	$P\mathrm{CO_2}$	Glucose
Potassium	$P\mathrm{O_2}$	Lactate
Chloride	$T\mathrm{CO_2}$	BUN/Urea
Ionized Calcium	Hematocrit	Creatinine
pH		

There are four 1.7 mL glass ampules of each level in the set.

Reactive Ingredients for TriControls Materials

Analyte	Calibration Verification Level 1	Calibration Verification Level 2 and Control Level 1	Calibration Verification Level 3 and Control Level 2	Calibration Verification Level 4 and Control Level 3	Calibration Verification Level 5
Na (mmol/L)	97	118	124	150	159
K (mmol/L)	2.30	3.00	4.00	6.30	8.20
Cl (mmol/L)	67	76	94	119	134
Glu (mg/dL)	595	285	160	65	53
Urea (mg/dL)	114	44	8.4	4.6	3.0
iCa (mmol/L)	0.40	0.90	1.35	1.58	2.40
Lac (mmol/L)	17.7	8.30	3.00	1.63	1.52
Crea (mg/dL)	15.6	4.65	1.59	0.65	0.55
$P\mathrm{CO_2}$ (mmHg)	96	65	40	26	12
$P\mathrm{O_2}$ (mmHg)	40	63	120	163	500
$\mathrm{H^+}$ (pH)	6.550	7.025	7.390	7.610	7.850

Storage

Refrigerated storage at 2-8 °C (35-46 °F) should be maintained until the printed expiration date on the box and ampule labels.

TriControls solutions may also be maintained at room temperature (18-30 °C; 64-86 °F) for up to 5 days.

Do not use TriControls solutions past the labeled expiration date on the box and ampule labels.

Ampule Use

When using cartridges that contain sensors for pH, $P\text{CO}_2$, $P\text{O}_2$ and ionized calcium, a separate ampule must be used for each cartridge being tested.

Do not use residual TriControls solution that may be in a syringe, ampule or capillary tube for additional testing of cartridges that contain sensors for ionized calcium, pH, $P\text{CO}_2$, or $P\text{O}_2$. However, cartridges without these sensors may be tested with remaining fluids if that testing is performed within 10 minutes of opening the ampule.

Best Results

For best results, ampules, cartridges and handhelds should be at the same temperature.

Before Use

i-STAT TriControls solutions require different temperature stabilization times depending on whether or not $P\text{O}_2$ is to be measured. If $P\text{O}_2$ is to be measured, equilibrate the ampule to room temperature for 4 hours prior to use. If $P\text{O}_2$ is not being measured, equilibrate the ampule for approximately 30 minutes at room temperature.

Procedure

STEP	ACTION
1	Access the Cal Ver option under Quality Tests in the Administration Menu. Enter the required information. The handheld allows 15 minutes (or the customized timeout) to insert the cartridge after the last data entry.
2	Immediately before use, shake the ampule vigorously for 5 to 10 seconds to equilibrate the liquid and gas phases. To shake, hold the ampule at the tip and bottom with forefinger and thumb to minimize increasing the temperature of the solution. If necessary, tap the tip of the ampule to send solution back into the bottom section of the ampule.
3	Protect fingers with gauze, tissue or glove, or use an ampule breaker to snap off the tip of the ampule at the neck.
4	Immediately transfer the solution from the ampule into a capillary tube or syringe, and then immediately transfer the solution into a cartridge.
5	Immediately seal the cartridge and insert it into a handheld – it is important not to expose the solution to room air since this will alter the results. **Note:** Since aqueous based solutions such as control materials lack the buffering capability of whole blood, the transfer process from ampule to cartridge must be more expedient than with a patient sample.

Transfer with Capillary Tube

Plain capillary tubes are recommended to transfer an aqueous calibration verification solution from the ampule to the cartridge. When using a capillary tube (fresh capillary tubes with sufficient fill capacity are recommended), fill from the bottom of the ampule to avoid drawing air into the capillary tube. Avoid drawing solution from the surface by placing a finger over the far end of the tube as it is inserted into the ampule. Once the open end of the tube rests at the bottom of the ampule, uncover the other end to allow filling by capillary action.

Art: 714377-00P

Transfer with Syringe

Plain syringes (fresh 1 mL or 3 mL sterile syringe with 16 – 20 gauge needles) are recommended to transfer aqueous calibration verification solutions from the ampule to the cartridge. When using a syringe, slowly draw approximately 1 mL of solution from the bottom of the ampule.

Acceptable Criteria

Target values (determined by testing multiple ampules of each level using multiple lots of cartridges and i-STAT handhelds that have passed the Electronic Simulator test) are printed on a Value Assignment Sheet posted on the APOC website at www.pointofcare.abbott.

Calibration throughout the reportable range of each analyte is verified if each analyte value falls within the corresponding range in the Value Assignment Sheet.

If a result for a level is outside the range published in the Value Assignment Sheet, two additional cartridge runs should be performed on this level and the three results averaged and then compared to the Value Assignment Sheet range. If this average value is still outside the acceptable range, troubleshooting may be required.

Note: If the Calibration Verification Set is to be used to assess linearity, plot the analyte value against the mean value of the acceptable range. The concentrations of analytes in the Calibration Verification Set are not intended or prepared to be equally spaced.

VERIFICATION PROCEDURE FOR HEMATOCRIT

Preparation of Hematocrit Sample

1. Draw 4 lithium heparin green top tubes from a fasting person with a normal hematocrit or MCHC. 7mL vacuum tubes are suggested. Label the tubes 1, 2, 3, and 4.

2. Centrifuge tubes 3 and 4 for 10 minutes at 3,000 rpm to pack the cells.

3. Remove two thirds the volume of whole blood from tube 1. This blood should be held in a clean plain tube in case it is needed to make adjustments later.

4. Transfer all of the plasma from tube 4 to tube 1.

5. Remove three fourths of the plasma from tube 3. This plasma should be held in a clean plain tube in case it is needed to make adjustments.

6. Gently invert tubes 1, 2 and 3 to resuspend the cells.

7. Measure the hematocrit of the blood in tubes 1, 2, and 3 using one cartridge for each tube. Adjust the hematocrit in tube 1 until it reads close to, but not less than, 15%. Adjust the hematocrit in tube 3 until it reads close to, but not more than, 75%.

Measurement

1. Gently invert tubes 1, 2, and 3 to resuspend the cells.

2. Measure the hematocrit of the blood in tubes 1, 2, and 3 three times each by the i-STAT and microcentrifuge methods.

3. Inspect the data for outliers. Repeat a measurement if necessary.

4. Calculate the mean of the three measurements of the three hematocrit levels for both methods.

Interpretation of Results	The i-STAT hematocrit method using blood anticoagulated with lithium heparin is calibrated to give results equivalent to the reference microhematocrit method using blood anticoagulated with K_3EDTA. Since the blood used for the microhematocrit determination here is anticoagulated with lithium heparin, adjustment must be made to the observed i-STAT values to compensate for the anticoagulant difference.

1. To calculate the adjusted i-STAT hematocrit mean, multiply the mean of the observed i-STAT results by 1.0425.

2. The adjusted i-STAT hematocrit mean should be within ±3%PCV of the microhematocrit mean.

   For example: the microhematocrit method mean for the mid level sample is 36%PCV. The i-STAT method mean is 34%PCV. 34 x 1.0425 = 35.445. Acceptable range for the adjusted i-STAT mean: 33 - 39%PCV.

Note: If your analyzers are customized for K_2EDTA/Heparin/None, the above calculation is unneccessary.

Notes on the Procedure

1. If a higher hematocrit value is needed in tube 1 or 3, packed cells can be obtained by centrifuging the whole blood retained from tube 1 in step 3. If a lower hematocrit value is needed, add plasma retained in step 5.

2. The highest hematocrit that should be tested on the i-STAT System is 75%. Whole blood samples with hematocrit values greater than 75% will be flagged as >75. The lowest hematocrit that should be tested on the i-STAT System is 15%. Whole blood samples with hematocrit values less than 15% will be flagged as <15.

Using Another Comparative Method

Methods other than the reference microhematocrit procedure may be used to verify calibration and reportable range of the i-STAT hematocrit. However, the following requirements apply:

- Blood should be drawn from a fasting donor with a normal hematocrit and a normal MCHC (calculated from hemoglobin and hematocrit values determined using reference methods) and be free of specific interferences which degrade the accuracy and/or precision of the alternative comparative method or the i-STAT method.

- Calculation of results must correct for any systematic bias between the reference microhematocrit method and the alternative comparative method selected.

Reference Method

CLSI recommends that the blood samples anticoagulated with Na_2EDTA or K_2EDTA be used for the microhematocrit method.* However, EDTA will interfere with the electrolyte measurements which are used in the calculation of hematocrit results on the i-STAT System.

* CLSI. *Procedure for Determining Packed Cell Volume by the Microhematocrit Method;* Approved Standard– Third Edition. NCCLS document H7-A3 (ISBN 1-56238-413-9). CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2000.

VERIFICATION PROCEDURE FOR ACT

See Technical Bulletin "i-STAT Celite and i-STAT Kaolin ACT Heparin Linearity Procedure."

CALIBRATION VERIFICATION FOR i-STAT cTnI, BNP, AND CK-MB CARTRIDGES

Intended Use:

The i-STAT cTnI, BNP, and CK-MB Calibration Verification Sets are intended for use as an assayed plasma material to verify the greater portion of the Reportable Range for i-STAT cTnI, BNP, and CK-MB cartridges.

There are two 1.0 mL plastic vials of each of the three levels in the set.

Notes:

- These calibration verification materials do not contain sodium azide as a preservative.
- These calibration verification materials do not require freezing.

Warnings and Precautions

Each plasma donor unit used in the manufacture of this product has been tested by FDA accepted methods and found negative/non-reactive for the presence of HBsAg and the antibody to HIV-1/2, HCV, HIV NAT, and HIV-1 Ag. While these test methods are highly accurate, they do not guarantee that all infected units will be detected. Because no known test method can offer complete assurance the hepatitis B virus, hepatitis C virus, human immunodeficiency virus (HIV) or other infectious agents are absent, all products containing human source material should be considered potentially infectious and handled with the same precautions used with patient specimens.

Bacterial contamination of the control can cause an increase in turbidity. Do not use the control material if there is visible evidence of microbial growth or gross contamination.

Storage and Stability

Calibration Verification material is ready to use and requires no reconstitution or frozen storage. The calibration verification materials are stable until the expiration date on the vial label when stored unopened at 2-8 °C (35-46 °F). Once opened, these calibration verification materials are stable for 30 days when stored tightly capped at 2-8 °C (35-46 °F).

Procedure

1. Access the Cal Ver option under Quality Tests in the Administration Menu. Enter the required information. The handheld allows 15 minutes (or the customized timeout period) to insert the cartridge after the last data entry.

2. Immediately before use, gently mix the contents of the vial to ensure homogeneity. Avoid foaming of the sample.

3. Open the vial and transfer a drop of the fluid into the i-STAT cartridge using the dropper tip, a plain capillary tube, plain syringe, or plastic transfer pipette. Tightly recap the vial and store it at 2-8 °C (35-46 °F).

4. Seal the cartridge and immediately insert it into the i-STAT 1 handheld.

Acceptable Criteria

Target values (determined by testing multiple vials of each level using multiple lots of cartridges and i-STAT handhelds that have passed the Electronic Simulator test) are printed on a Value Assignment Sheet posted on the APOC website at www.pointofcare.abbott.

The Value Assignment Sheet displays target values and ranges expected when cartridges, calibration verification materials and equipment are performing properly.

Always ensure that the lot number and software revision on the Value Assignment Sheet match the lot number of the vial in use and the software revision in the analyzer.

Target values are specific to the i-STAT System. Results may differ if used with other methods.

If a result for a level is outside the range published in the Value Assignment Sheet, two additional cartridge runs should be performed on this level and the three results averaged and then compared to the Value Assignment Sheet range. If this average value is still outside the acceptable range, see the Troubleshooting section below for additional procedures to follow.

PROCEDURE FOR CARTRIDGES

Initiating Calibration Verification tests from the Quality Tests menu allows results to be stored in separate categories for the purpose of documentation and review. Also, measurement limits are not applied to results in this test path. Therefore, results below and above the measurement ranges will be reported.

- **DO NOT insert cartridge to start test.**

- **DO NOT open cartridge pouch before scanning the barcode.**

- **If Quality Check Code 69 or 140 appears, see Analyzer Coded Messages Technical Bulletin for Troubleshooting Information.**

1. Press ⏻ to turn on handheld.

2. Press MENU → 3 → 3 for Cal Ver Samples.

3. Follow handheld prompts.

4. Scan the lot number on the cartridge pouch.

   - Position barcode 3 - 9 inches from scanner window on the handheld.

   - Press and hold SCAN to activate the scanner.

   - Align the red laser light so it covers the entire barcode.

   - The handheld will beep when it reads the barcode successfully.

5. Continue normal procedures for preparing the sample, filling and sealing the cartridge.

6. Push the sealed cartridge into the handheld port until it clicks into place. Wait for the test to complete.

   Note: For ACT, PT/INR, Hct, and immunoassay testing, the handheld must remain on a level surface with the display facing up during testing. A level surface includes running the handheld in the downloader/recharger.

7. Review results.

Troubleshooting Cartridge Tests

See Troubleshooting Out-of-Range Results for Cartridges paragraph in the Performing Control Tests on Cartridges section of this manual.

Purpose

Samples from external quality control providers can be used to assess consistency of results for a particular method or system across testing sites. Due to matrix effects and additives, these samples should not be used as an indication of the system's true accuracy.

General Procedure for Cartridges

Initiating Proficiency Tests from the Quality Tests menu allows results to be stored in separate categories for the purpose of documentation and review. Proficiency samples should be tested in the same way as patient samples.

The same CLEW is used for the patient test path and the Proficiency test path. The Proficiency test path uses K_3EDTA standardization coefficients for Hematocrit and disables the CPB mode. It also uses the PREWARM mode for ACT. This ensures that hematocrit and ACT results are consistent across all sites. Also, if star-outs occur frequently when using the patient sample test path to test proficiency or external quality control samples, they might be avoided by using the proficiency test path.

- **DO NOT insert cartridge to start test**

- **DO NOT open cartridge pouch before scanning the barcode** (if applicable)

- **If Quality Check Codes 69, 140, or 147 appear, see Analyzer Coded Messages Technical Bulletin for Troubleshooting Information**

1. Press (|) to turn on Handheld.

2. Press MENU → 3 → 2 for Proficiency Samples

3. Follow Handheld prompts.

4. Scan the lot number on the cartridge pouch.
   - Position barcode 3 - 9 inches from scanner window on the Handheld.
   - Press and hold SCAN to activate the scanner.
   - Align the red laser light so it covers the entire barcode.
   - The Handheld will beep when it reads the barcode successfully.

   Note: If the cartridge pouch does not have a barcode, enter the lot number manually using the numbered keys or press ENT to bypass this prompt. You may ignore any letters in the lot number.
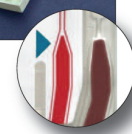
5. Continue normal procedures for preparing the sample, filling and sealing the cartridge.

6. Push the sealed cartridge into the Handheld port until it clicks into place. Wait for the test to complete.

   Note: For ACT, PT/INR, Hct, and immunoassay testing, the Handheld must remain on a level surface with the display facing up during testing. A level surface includes running the handheld in the downloader/recharger.

7. Review results

Troubleshooting

The i-STAT System is designed to measure fresh whole blood samples. Matrix effects and interfering substances can be expected when measuring non-whole blood samples. The following points should be considered when selecting and testing external quality control samples:

- Aqueous samples intended to assess blood gases will not be measured by the i-STAT System unless electrolytes, or at least sodium, are present.

- Fluorocarbon samples are not compatible.

- Preserved-cell samples are not compatible.

- Aged serum and lyophilized serum may contain degradation products or preservatives that interfere with the measurements.

- Matrix effects between aqueous-based and protein-based samples may cause results from the i-STAT System to differ from reference methods or other comparative methods.

- Aqueous samples that contain a resistive substance to allow assessment of conductometric hematocrit measurements will cause the i-STAT System to extrapolate ambient temperature results to 37 °C results for pH and PCO_2 as if the sample were whole blood. Since extrapolation coefficients for aqueous and whole blood samples differ, results on the i-STAT System for these samples may not agree with other methods.

While the various cartridges give the same results for whole blood samples, there may be small differences between generations and types of cartridges for non-whole blood samples. Generation means major manufacturing changes such as making the chips smaller. Cartridge types means those that make measurements at ambient temperature and those that make measurements at 37 °C.

Administrative errors include choosing the wrong method or peer group and transcription errors.

Drying a Wet Analyzer or Downloader

If the analyzer is placed on a wet surface or if any liquid is spilled onto it, dry the analyzer immediately. If liquid enters the following compartments, the analyzer may be damaged:

- ✧ The electronics compartment
- ✧ The battery compartment
- ✧ The cartridge port

The Downloader may also be damaged by liquid contamination. Unplug the power supply from the outlet and dry the Downloader completely.

Cleaning the Analyzer and Downloader

Clean the display screen and the case using a gauze pad moistened with any of the following:

- ✧ A mild non-abrasive cleaner
- ✧ Detergent
- ✧ Soap and water
- ✧ Alcohol
- ✧ 10% bleach solution
- ✧ PDI® Super Sani-Cloth® (solution of IPA, n-Alkyl dimethyl ethylbenzyl- and benzyl- ammonium chloride)

Rinse the case using another gauze pad moistened with water and dry. Avoid getting excess fluids in the seam (A) between the display screen and the case.

The use of any unapproved product to clean the i-STAT System may result in damage to system components.

Wash hands throughly with soap and water after handling an analyzer or downloader.

(PDI and Sani-Cloth are registered trademarks of Sani-System™ Brand Products, the Health Care Division of Nice-Pak Products, Orangeburg, NY, USA.)

Caution

Exercise universal safety precautions at all times when handling the analyzer, cartridges, and peripherals to prevent exposure to blood-born pathogens.

The analyzer and downloader are NOT designed to be autoclaved or sterilized by any other method, including high heat, irradiation, or gaseous chemical processes. The analyzer and downloader MUST NOT be immersed in any liquid.

Dispose of analyzer, peripheral electronics, and batteries according to local, state, and/or national guidelines.

If the analyzer is not to be used for an extended period of time, the batteries should be removed to prevent leakage.

Decontaminate the analyzer or Downloader whenever a specimen is spilled onto it or if the item is to be returned to APOC for repair. Wear gloves while performing the following procedure.

Procedure	STEP	ACTION
	1	Prepare a 1:10 solution of household bleach by mixing one part of bleach with nine parts of tap water. This solution will maintain its germicidal action for a week.
	2	Soak a few gauze pads in the bleach solution. Before use, squeeze the pads to remove excess solution.
	3	Soften, then remove any dried blood with one or two of the gauze pads soaked in the bleach solution. Avoid scraping dried blood as contaminated particles may become airborne.
	4	Clean the entire surface of the device twice with gauze pads soaked in the bleach solution.
	5	Rinse the surface of the device with gauze pads moistened with tap water and dry.
	6	If the device is to be shipped, place it in a plastic bag.

Removing and Replacing Disposable Batteries

Wait until any test in progress is completed, and turn off the analyzer before replacing the batteries or the most recent set of results may be lost. Stored results will not be lost when replacing the batteries.

STEP	ACTION
1	Slide the battery compartment door off.
2	Tilt the analyzer slightly to slide out the battery carrier which contains the two 9-volt batteries.
3	Remove the old batteries from the carrier. Pull each battery out to the side and then lift back and out.
4	Note the battery orientation symbol molded into the carrier on each side of the center wall. Starting with one side, orient the new battery so it matches the symbol. Slide the battery into the carrier, pushing the terminal end in first, under the plastic bar, and slide it up as far as it will go. Then push the bottom of the battery inward. The terminals of the battery should be underneath the protective bar on the carrier. Repeat for the second battery on the other side of the carrier.
5	Note the orientation of the battery carrier illustrated on the label on the carrier. The label faces up, and the electrical contact end of the carrier goes into the instrument first. Insert the carrier into the instrument as shown on the label. If the carrier is inserted incorrectly, the battery door will not close.
6	Slide the battery compartment door back into place.

Caution

A falling instrument may cause injury. Place the instrument on a flat and stable surface at all times to ensure the instrument does not fall.

Removing and Replacing the Rechargeable Battery

Wait until any test in progress is completed, and turn off the analyzer before replacing the battery or the most recent set of results may be lost. Stored results will not be lost when replacing the batteries.

STEP	ACTION
1	Slide the battery compartment door off.
2	Tilt the analyzer slightly to slide out the rechargeable battery pack.
3	The battery pack has two labels: one for orientation in the analyzer and one for orientation in the Downloader/Recharger. With the label with the analyzer facing up, and the electrical contact end of the pack facing the analyzer, insert the pack into the analyzer as shown on the label. If the pack is inserted incorrectly, the battery door will not close.
4	Slide the battery compartment door back into place.
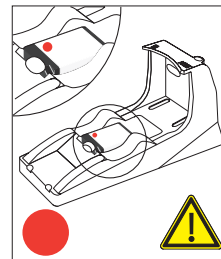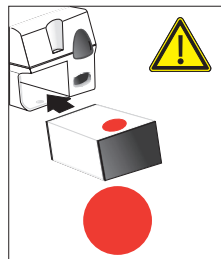
For instructions on updating your i-STAT® 1 Handheld, please refer to the following Technical Bulletins directly following section 18 in your i-STAT 1 System Manual:

1. INSTRUCTIONS FOR UPDATING i-STAT 1 HANDHELD SOFTWARE USING www.abbottpointofcare.com (Art. 731335-00B)

2. NETWORK OPTIONS FOR UPDATING THE i-STAT 1 HANDHELD USING www.abbottpointofcare.com (Art. 731336-00B)

i-STAT®
TECHNICAL BULLETIN

INSTRUCTIONS FOR UPDATING i-STAT® 1 HANDHELD SOFTWARE USING www.abbottpointofcare.com

Overview

This Technical Bulletin has been created specifically to guide you through the process of updating the software on your i-STAT® 1 Handheld(s). This process should take less than 10 minutes for the first Handheld, and less time for additional Handhelds.

Why Do i-STAT Handhelds Need Software Updates?

The i-STAT 1 System is designed to eliminate operator influence on delivered results.

Due to the continuous manufacturing process improvements to the i-STAT System, it is necessary to update standardization values from time to time to maintain long-term consistency of performance. These updates are equivalent to manually adjusting calibration on a traditional laboratory analyzer.

New CLEW software—delivered twice a year —re-establishes these standardization values and incorporates refinements to the internal quality monitoring system. New JAMS application software allows the i-STAT 1 Handheld to recognize any newly launched cartridge types and to perform any newly launched features.

JammLite Process Overview

Whether updating one, two, or many i-STAT 1 Handheld(s), the JammLite procedure must be used to update the first i-STAT 1 Handheld. This process is noted in the diagram below.

Gather Equipment for JammLite → Connect/Set Up Equipment → Load JAMS/CLEW → Update i-STAT 1 Handheld → Verify Software Update

00:00   10:00

Abbott
Point of Care
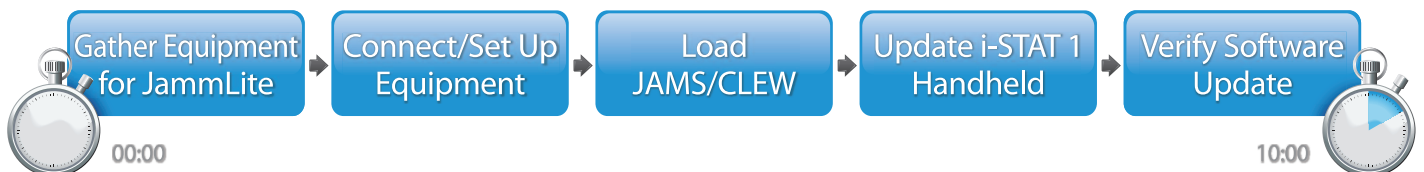
Optional Steps

Once the first i-STAT 1 Handheld has been updated using the JammLite Utility, additional i-STAT 1 Handhelds may be updated the same way or by using the Handheld-to-Handheld method. Additionally, if using Central Data Station (CDS), the new software must be added to the CDS Customization Workspace.

| **1. Update with JammLite Utility** | or | **2. Update with the Handheld-to-Handheld Process** | or | **3. Update Central Data Station Customization Workspace** |
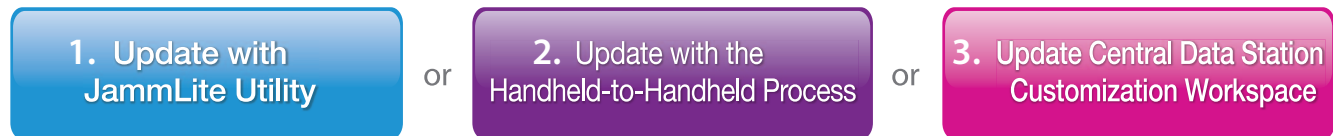
Choosing the Best i-STAT 1 Handheld Update Method

JammLite

Always update the first i-STAT 1 Handheld using the JammLite method. It's best to update all Handhelds via JammLite if they are readily available and near the PC you will use to run JammLite.

Handheld-to-Handheld

The Handheld-to-Handheld method is a good choice after the first Handheld has been updated via JammLite and other Handhelds that need updating are not near the PC that was used to run the JammLite Utility.

CDS

Users of i-STAT Central Data Station, or i-STAT/DE with either Medical Automation Systems RALS-Plus® or Abbott Diabetes Care PrecisionWeb® who would like to update i-STAT 1 Handhelds via the data management software, please consult "Network Options for Updating the i-STAT 1 Handheld using www.abbottpointofcare.com" (i-STAT Technical Bulletin 731336).

Instructions for Using This Technical Bulletin

Color-Coded Sections

This bulletin contains color-coded sections to easily identify the steps associated with the different methods for updating i-STAT 1 Handhelds and updating the Central Data Station Customization Workspace.

Color-Coded, Numbered Steps

As stated above, there are several options for updating i-STAT 1 Handhelds. The color-coded, numbered steps help guide the user through a selected update process, as well as provide direction within the bulletin should the user encounter a technical issue, or need to repeat a step. For example, 2 indicates section 2 (Handheld-to-Handheld update method).

Tips for Troubleshooting

Troubleshooting tips are incorporated throughout the technical bulletin where needed. These tips are identified by the ⚠ icon, and appear on the right side of the page.

Follow these steps to update with the JammLite Utility

Gathering Equipment for JammLite

i-STAT 1 JammLite Utility

1.1 Before starting the process make sure all the required equipment is available:

- Computer with:
    - Windows 2000, Windows XP or Windows 7
    - A 9-pin serial port or USB port (if using a DRC-300)
    - Access to:
      http://www.abbottpointofcare.com/SoftwareUpdate
- i-STAT System Equipment:
    - (1) Serial Downloader/ Recharger (DRS-300) or DRC-300
           or
    - (2) Serial Downloader (DS-300)
    - (3) Downloader power supply
    - (4) i-STAT 1 Handheld
    - (5) 9-Pin null modem serial cable supplied with the DS-300 or DRS-300 downloader
    - (6) USB cable supplied with the DRC-300
    - (7) Electronic Simulator

> ⚠ When using a DS-300 or DRS-300, a computer with a traditional 9-pin serial port is required. If the computer does not have one, follow your internal technical support procedure (i.e., contact the IT Department or the individual in your office responsible for computer support). Indicate that the i-STAT 1 software update process requires:
>
> - a 9-pin serial port
>
> Need technical support?
> Call Abbott Point of Care (APOC) Technical Support:
>
> - Hospital-based customers call: 1-800-366-8020 option 1
> - All other customers call: 1-800-284-0702 option 1
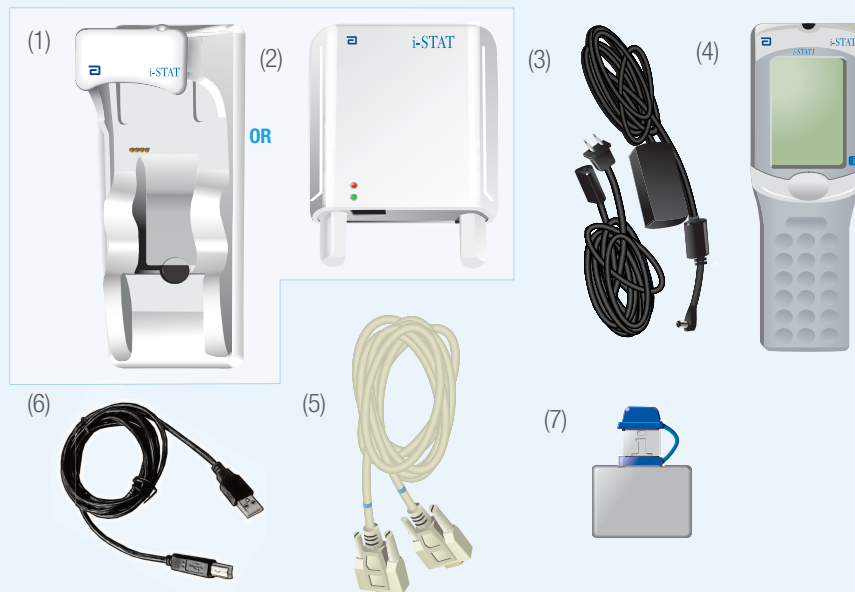
1.2 Ensure your i-STAT 1 Handheld has enough battery power (7.5 volts or higher).

To do this:
- Press the **On/Off** (⏻) key
- Press the **MENU** key
- Press **1** for Analyzer Status
- Confirm the battery voltage

⚠ If you have rechargeable batteries, charge your Handheld until it has at least 7.5 volts.

Rechargeable Batteries

⚠ If you have disposable batteries, replace with fresh ones.

Disposable Batteries

Connecting/Setting Up Equipment

i-STAT 1 JammLite Utility

1.3 If using a Serial Downloader or Serial Downloader/Recharger, connect the i-STAT 1 Serial Downloader to the 9-pin serial port on the back of the computer with the 9-pin null modem serial cable as shown.

If using a DRC-300, connect the DRC-300 to the USB port on the back of the computer with the USB cable as shown. **Note**: These instructions assume that the DRC-300 has already been installed per Art. 728690: "The i-STAT 1 Downloader/Recharger (model number DRC-300)" for serial communications.
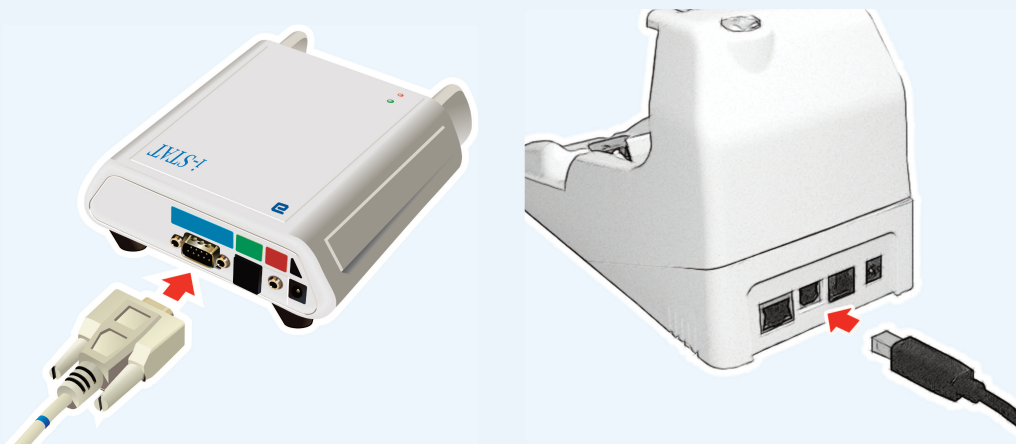
1.4 Connect the power supply:

- to the i-STAT 1 Serial Downloader or Serial Downloader/Recharger, and

- to a wall outlet or power strip
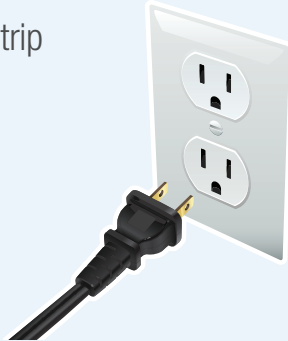
⚠ When power is supplied to the Serial Downloader, a green light will illuminate.

When power is supplied to the Serial Downloader/Recharger or DRC-300, it will look as it did before power was supplied.

Loading JAMS/CLEW   i-STAT 1 JammLite Utility

1.5 Close all open programs on the computer including i-STAT Central Data Station (if applicable).

1.6 Navigate to www.abbottpointofcare.com/SoftwareUpdate.

1.7 Select Language from the drop down menu.

1.8 If prompted, indicate the type of Data Management (if any) used with the i-STAT System. Otherwise, proceed to Step 1.9.

1.9 When prompted, click on the software file link (SUXXXXXX.exe) and save file to:

- Desktop, or

- If you use CDS Version 5, save the file to the c:\bins directory. If the c:\bins directory does not exist, a bins folder will need to be created under the c: drive.

Close the "Download Complete" window.

1.10 Navigate to saved file location. Double click the software file "SUXXXXXX.exe".

1.11 Click Run. If a Command window opens prompting to overwrite, answer "Y" and then press Enter. Continue answering "Y" to all prompts that appear until the Command window closes. From among the icons that appear, double click ▮▮JAMMLITE.EXE

> ⚠ If the JammLite program does not launch or you receive an error message, contact APOC Technical Support and tell the support specialist you are unable to complete step **1.11** of this document.

Updating Your i-STAT 1 Handheld   i-STAT 1 JammLite Utility

1.12 In the JammLite utility, select the **i-STAT 300 Analyzer** within the Instrument dropdown menu.

```
JammLite 4.3                                  ✕

Instrument
I-STAT 200 Analyzer           ▼
   I-STAT 200 Analyzer
➡  I-STAT 300 Analyzer
   Blood Analysis Module
IP Address                               ✔ Update


Application
JAMSXXXX.BIN                  ▼
CLEW
AXX.CLW                       ▼          ▮ Exit
```
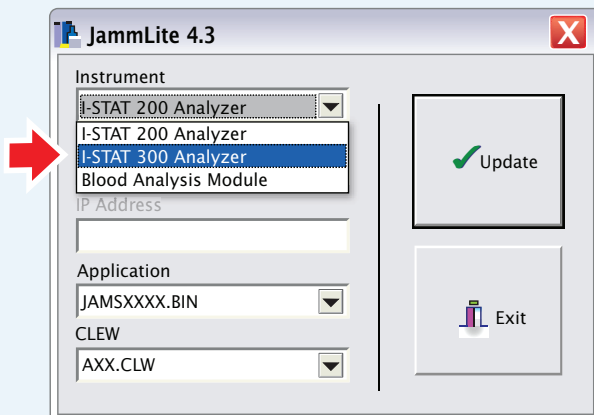
1.13 By default, the lowest numbered COM port will automatically be selected.

If the downloader is connected to a different COM port, change the selection to that COM port now.

JammLite 4.3 ✕

Instrument
I-STAT 300 Analyzer ▼

Port
COM1 ▼

IP Address

Application
JAMSXXXX.BIN ▼

CLEW
AXX.CLW ▼

✔Update

🔳 Exit
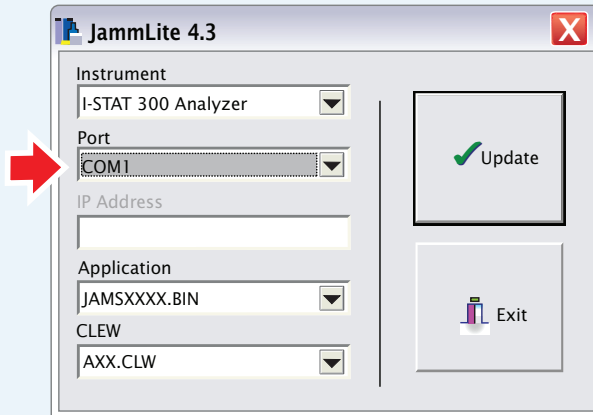
⚠ If no ports are displayed, close all open programs including JammLite, and then re-launch JammLite.

If JammLite still has no available COM ports listed, call APOC Technical Support for assistance.

1.14 Check that the **Application** and **CLEW** listings match those in the Product Update.

Click the **Update** button.

JammLite 4.3 ✕

Instrument
I-STAT 300 Analyzer ▼

Port
COM1 ▼

IP Address

Application
JAMSXXXX.BIN ▼

CLEW
AXX.CLW ▼

✔Update

🔳 Exit

Note: Application and CLEW numbers are for example only. The "numbers" have been replaced with X's in the example above and will change with each software update.
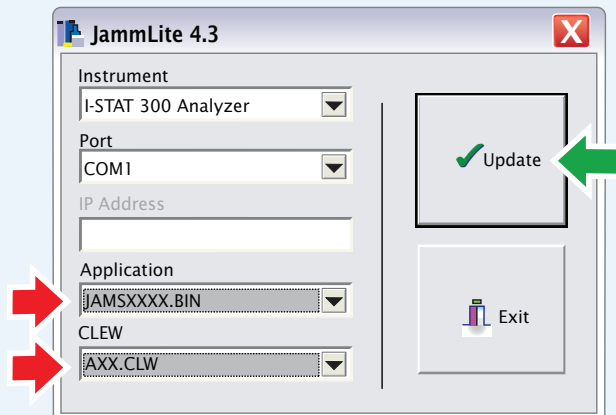
⚠ If an error occurs, check the serial connection between the downloader and the PC, as well as the power connection to the downloader.

If connected correctly, select a different COM port **(Do not select TCP/IP)** within the dropdown menu and click **Update**.

If errors persist after trying each of the COM ports listed in JammLite, verify the serial number of your downloader and call APOC Technical Support for assistance.

1.15 Follow the onscreen instructions.

1) If an analyzer is already in the Downloader remove it.

2) Ensure the analyzer to be updated is off.

3) Place the analyzer in the Downloader.*

[Cancel]

*If using the Serial Downloader/Recharger, a **blue light** will illuminate when the Handheld is placed correctly within it.
If using the Serial Downloader, a **red light** will illuminate when the Handheld is placed correctly within it.

1.16 When the update is in progress, the following screen will appear:

The application update is in progress.

Please do not remove the analyzer from the Downloader.

[Cancel]

Programming application block 108/2055

⚠ If you do not see the screen shown on the left—

—acknowledge the error message(s) and click **OK**.

Return to Step 1.14

The Receiving Handheld will have 1's and 0's streaming across the screen signifying that it is receiving the software.

i-STAT
i-STAT1

0100111 0110001 0
00110001 00111001
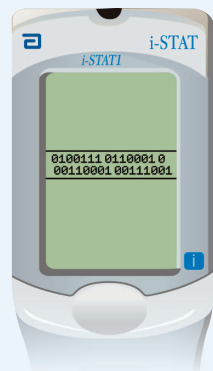
Do not move the Handheld until the success screen is displayed.

The application update was successful.

The CLEW update was successful.

[Close]

1.17 Run the Electronic Simulator in the Handheld.

When the simulator finishes, PASS should be displayed.

ID:54102

12:14 31 MAR 09

ELECTRONIC
SIMULATOR

PASS

1 - Test Options

> ⚠ If **PASS** is not displayed,
> re-run the Electronic Simulator.
> If the repeated Electronic
> Simulator attempt fails, please
> contact APOC Technical Support.

> ⚠ For additional information on
> running the electronic simulator,
> please see:
>
> - Section 14 of the i-STAT 1
>   System Manual, or
> - The Introduction and Start-up
>   section of the i-STAT System
>   Manual for Waived Tests

Congratulations. The process for updating the first i-STAT 1 Handheld is complete.

Review the options below for additional instructions.

If there are no additional Handhelds to update, the process is complete:

- Click the **X** button in the upper right corner of the software screen
- Close all other open boxes
- Confirm all messages

If there are additional Handhelds to update via JammLite:

- Click **Close**
- Click **Update**
- Repeat Steps **1.14** through **1.17**

If there are additional handhelds to update with the Handheld-to-Handheld process:

- Go to **2. Update with the Handheld-to-Handheld Process** on page 11

If your facility uses Central Data Station:

- You must proceed to **3. Update Central Data Station Customization Workspace** on page 16.

After updating the first i-STAT 1 Handheld, follow these steps to update additional Handhelds with the Handheld-to-Handheld Process

Gathering All Equipment   Handheld-to-Handheld

2.1 Before starting the process make sure all the required equipment is available:

- Recently updated i-STAT 1 Handheld (referred to in this section as the Sending Handheld) charged to 7.5 volts or higher*

- The Handheld unit to be updated (referred to in this section as the Receiving Handheld) charged to 7.5 volts or higher*

- Electronic Simulator
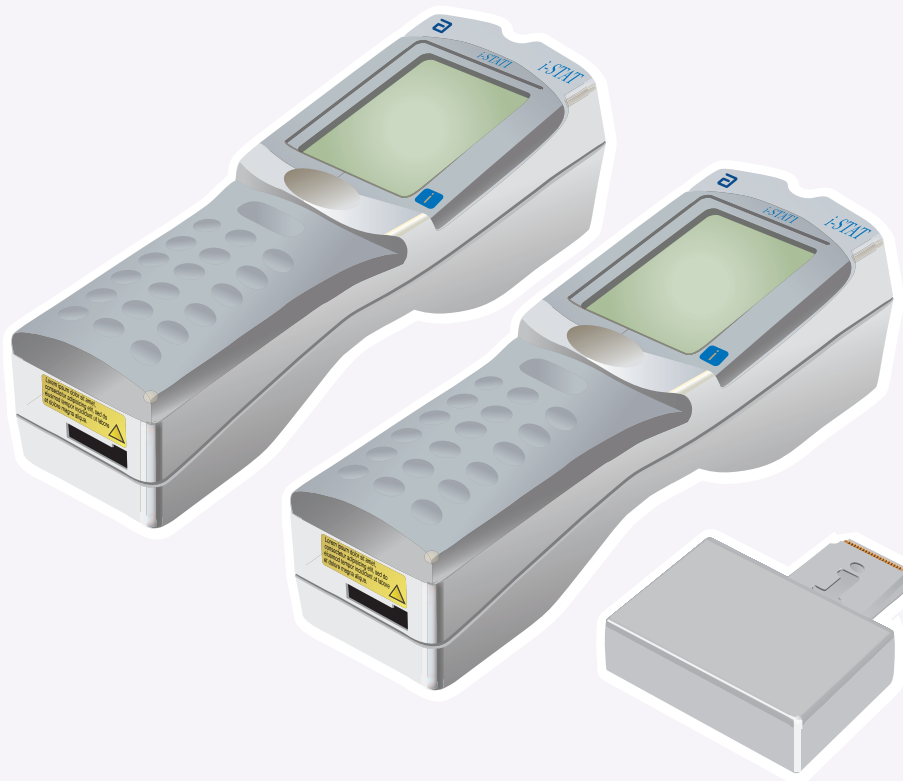
* For information on checking battery power, see page 4, step **1.2**

2.2 Make sure the power is **off** on the Receiving Handheld.

2.3 Place Sending and Receiving Handhelds on a flat surface with infrared (IR) windows aligned, approximately 1 foot apart.

1'

Receiving Handheld
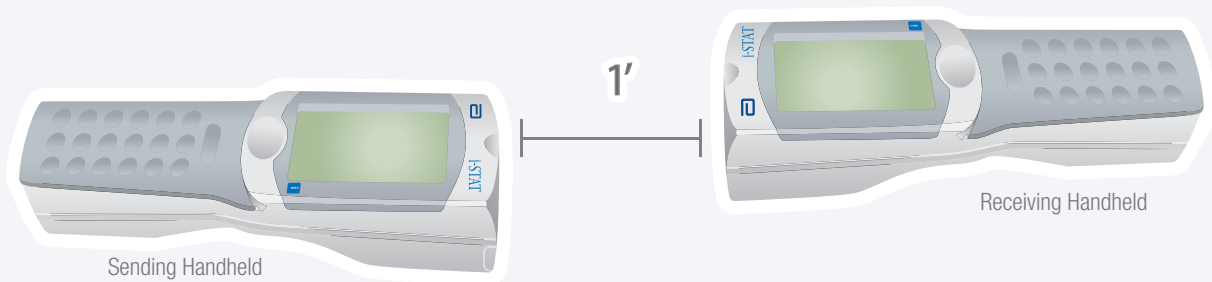
Sending Handheld

2.4 Turn **on** the Sending Handheld, press **MENU**, and select **7-Utility**.

2.5 When prompted for a password, press **ENT** and continue.

i-STAT

i-STAT1

Enter Password

-----

i
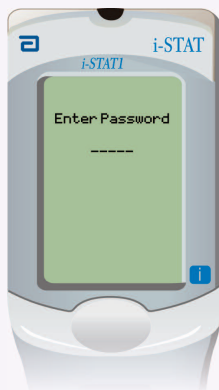
Note: Abbott Point of Care Inc. recommends changing the default password.

⚠ If the correct password was not entered, the Utility Menu will not appear. Check for data entry errors and retry.

If still unsuccessful, call APOC Technical Support and indicate:

- A Handheld-to-Handheld update has been attempted

- Password for Utility Menu is unknown

If that did not work, a password is needed.

Enter the password defined by your facility and press **ENT**.

2.6 In the Utility Menu:
- Press **1-SEND SOFTWARE**
- Press **1-JAMSXXX/AXX**

  Note: The "numbers" have been replaced with X's in the example above and will change with each software update.

  Make sure the Receiving Handheld's power is **off**.

2.7 When the Sending Handheld displays **WAITING TO SEND**:
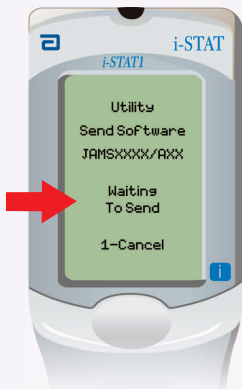
- Keep the infrared windows aligned
- Without lifting either Handheld off the flat surface, move the Receiving Handheld towards the Sending Handheld until the Sending Handheld displays **SENDING**

Receiving Handheld
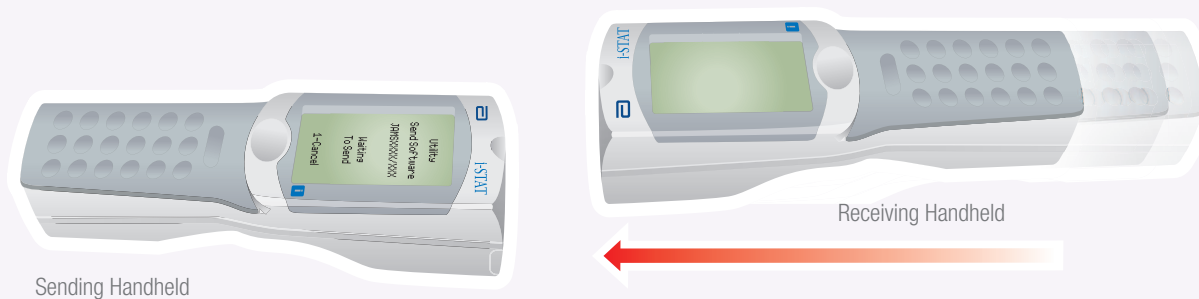
Sending Handheld

2.8 When the update is in progress, the Sending Handheld will display **SENDING** along with a bar indicating that the software is being sent.
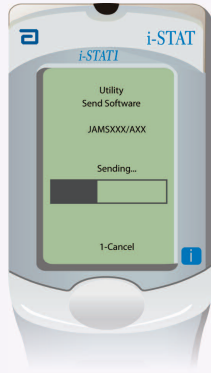
i-STAT
i-STAT1

Utility
Send Software

JAMSXXX/AXX

Sending...

1-Cancel

The Receiving Handheld will have 1's and 0's streaming across the screen signifying that it is receiving the software.

i-STAT
i-STAT1

0100111 0110001 0
00110001 00111001
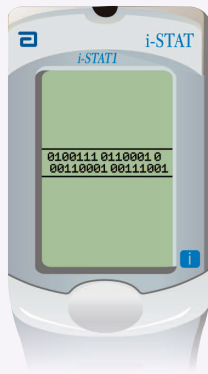
Do not move the Handhelds until the Sending Handheld goes back to the Utility menu, and displays **Last Send Successful.** The update is now complete.

i-STAT
i-STAT1

Utility
Send Software

1-JAMSXXXX/AXX
2-CLEW AXX
3-Cancel

Last Send
JAMSXXXX/AXX
Successful
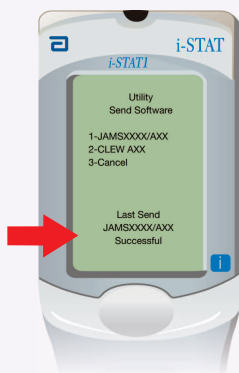
2.9

Run the Electronic Simulator in the newly updated Handheld.

When the simulator finishes, PASS will be displayed.
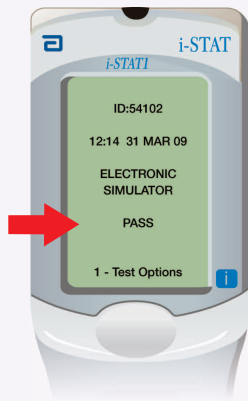
> ⚠ If **PASS** is not displayed, re-run the Electronic Simulator. If the repeated Electronic Simulator attempt fails, please contact APOC Technical Support.

> ⚠ For additional information on running the electronic simulator, please see:
> - Section 14 of the i-STAT 1 System Manual, or
> - The Introduction and Start-up section of the i-STAT System Manual for Waived Tests

Congratulations. The process for updating an additional i-STAT 1 Handheld is complete.

If there are other i-STAT 1 Handhelds to update, repeat steps **2.2** through **2.9**

If there are no other Handhelds to update, the process is complete.

Follow these steps to update the Central Data Station Customization Workspace

Central Data Station is an optional software component used to collect data from i-STAT Handhelds.

Determining CDS Update Path — JAMS/CLEW in Central Data Station

3.1 Before starting the process, choose the appropriate CDS update path:

Are you attempting to update CDS on the PC that was used to update the i-STAT 1 Handhelds with Jammlite?

If "Yes," continue with step **3.2**

If "No," (CDS is NOT installed on the PC that was used with JammLite) go to page 19.

⚠ If you have a version of CDS other than version 5, please contact APOC Technical Support.

Connecting/Setting Up Equipment — JAMS/CLEW in Central Data Station

3.2 Launch the CDS application and select:

- **Main**
- **Open Administration Function**
- **Customization**

Main	System	Tools	Window	Help	
Open Monitor			▶		
Open Administration Function			▶	Instrument/Location	
Open Data Viewer			▶	Operator	
Open Report			▶	Database Maintenance	
Close			▶	Inventory	
				Customization	
Exit		Alt+x		User Administration	

3.3 Type **istat** as the Customization Password and click **OK.**

> **Note:** Abbott Point of Care Inc. recommends changing the default password.
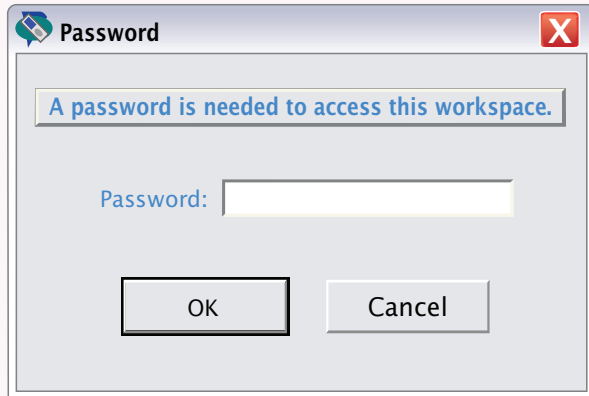
> ⚠ If you are unable to open CDS Customization, please contact APOC Technical support and indicate that your CDS Customization Password is unknown.

3.4 Under the "Default customization profile:" column, double click on the "**i-STAT Analyzer CLEW:**" button.
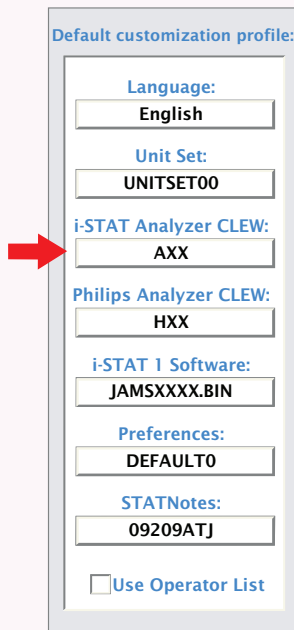
> ⚠ If the latest CLEW version is not available, attempt to reinstall CLEW by going to pages 5–7 of the JammLite Utility section and complete steps **1.7** through **1.10**

Default customization profile:

Language:
English

Unit Set:
UNITSET00

i-STAT Analyzer CLEW:
➡ AXX

Philips Analyzer CLEW:
HXX

i-STAT 1 Software:
JAMSXXXX.BIN

Preferences:
DEFAULT0

STATNotes:
09209ATJ

☐ Use Operator List

Note: CLEW and JAMS numbers are for example only. These numbers change with each software update.

3.5 The latest CLEW should be displayed in the i-STAT Analyzer CLEW window.

Select the **CLEW** version that matches the Product Update and click **OK.**
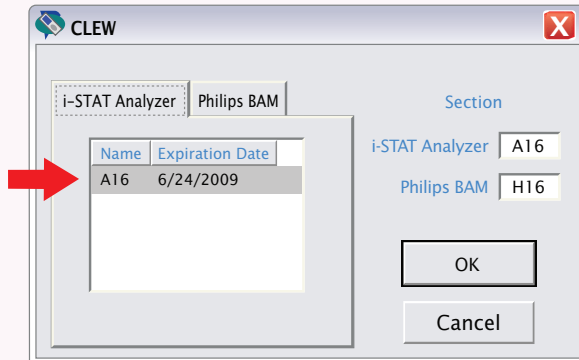
Click **YES** for the confirmation message.

3.6 If "Use Default Profile" is not checked beside any location-based customization profile, double click the corresponding box under the i-STAT Analyzer CLEW column.

Location-based customization profiles:							
Location	**Enable Updates**	**Use Default Profile**	**Update CLEW**	**i-STAT Analyzer CLEW**	**Philips BAM CLEW**	**Preferences**	**STATNotes**
A_1	✓	☐	✓	A16	H16	DEFAULT0	CHART0

The latest CLEW should be displayed in the i-STAT Analyzer CLEW window.
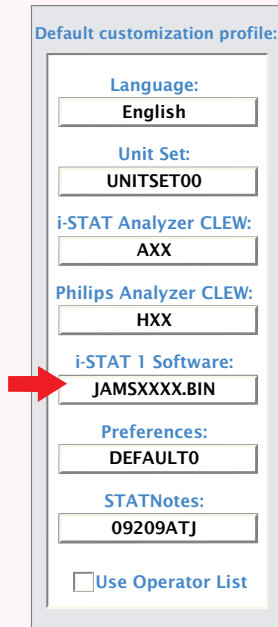
Select the **CLEW** version that matches the Product Update and click **OK**.

Click **YES** for the confirmation message.

3.7 Underneath the "Default customization profile:" column:

- Double click on the "**i-STAT 1 Software:**" button
- Select the JAMS version that matches the Product Update

- Click **OK**

Default customization profile:

Language:
English

Unit Set:
UNITSET00

i-STAT Analyzer CLEW:
AXX

Philips Analyzer CLEW:
HXX

i-STAT 1 Software:
JAMSXXXX.BIN

Preferences:
DEFAULT0

STATNotes:
09209ATJ

☐ Use Operator List

Congratulations. You have successfully assigned JAMS/CLEW in your Central Data Station.

CDS is not installed on the PC used with JammLite

If CDS is not installed on the PC that was used with the JammLite Utility:

- Go to the PC where CDS is installed

- Go to pages 5–7 of the JammLite Utility section and complete steps **1.6** through **1.10**

- When complete, proceed to the CDS Customization section pages (16–19) and complete steps **3.2** through **3.7**
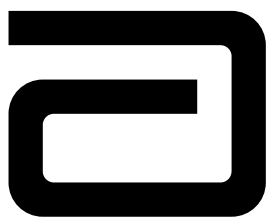
i-STAT®
TECHNICAL BULLETIN

NETWORK OPTIONS FOR UPDATING THE i-STAT® 1 HANDHELD USING
www.abbottpointofcare.com

OVERVIEW

This Technical Bulletin has been created specifically to guide you through the process of updating the software on the i-STAT® 1 handheld(s) using one of four network options:

1. Using a Network Downloader, Downloader/Recharger, or DRC-300 and the JammLite process with TCP/IP

2. Using the Central Data Station (CDS) Version 5 Customization Workspace with a Serial or Network Downloader, Downloader/Recharger, or DRC-300

3. Using a Serial Downloader or a serially connected DRC-300 and the JammLite process for accounts with RALS-Plus and i-STAT/DE

4. Using the i-STAT/DE Customization Workspace and a Network Downloader, Downloader/Recharger, or DRC-300

Before beginning, check the Analyzer Status page and verify that the i-STAT 1 handheld has enough battery power (7.5 volts or higher).

WHY DO i-STAT HANDHELDS NEED SOFTWARE UPDATES?

The i-STAT System is designed to eliminate operator influence on delivered results.

Due to continuous manufacturing process improvements to the i-STAT System, it is necessary to update standardization values from time to time to maintain long-term consistency of performance. These updates are equivalent to manually adjusting calibration on a traditional laboratory analyzer.

New CLEW software -- delivered twice a year -- re-establishes these standardization values and incorporates refinements to the internal quality monitoring system. New JAMS application software allows the i-STAT handheld to recognize any newly launched cartridge types and to perform any newly launched features.

Abbott
Point of Care

1. UPDATE PROCEDURE USING A NETWORK DOWNLOADER AND THE JammLite PROCESS WITH TCP/IP

1.1: Before starting the process, make sure all the required equipment / information is available.

- **Computer with:**

    - Windows 2000, XP, or Windows 7

    - Access to http://abbottpointofcare.com/softwareupdate

- **i-STAT System Equipment**

    (1) Network Downloader, Downloader / Recharger, or DRC-300

    Note: These instructions assume that the Network Downloader types used for the update process are already installed and in use on the customer's network.

    (2) i-STAT 1 handheld

    (3) Electronic Simulator

- **List of the IP Address(es) for the network downloader(s) to be used for the software update process**

1.2: Close all open programs on the computer including i-STAT Central Data Station (if applicable).

1.3: Navigate to www.abbottpointofcare.com/SoftwareUpdate.

1.4: Select Language from the drop-down menu.

1.5: If prompted, indicate the type of Data Management (if any) used with the i-STAT System. Otherwise, proceed to Step **1.9**.

1.6: When prompted, click on the software file link and save file to:

- Desktop, or

- If you use CDS Version 5, save the file in the c:\bins directory. If the c:\bins directory does not exist, a bins folder will need to be created under the c: drive.

Close the "Download Complete" window.

1.7: Navigate to saved file location. Double click the software file "SUXXXXXX.exe".

1.8: Click Run. If a Command window opens prompting to overwrite, answer "Y" and then press Enter. Continue answering "Y" to all prompts that appear until the Command window closes. From among the icons that appear, double click .

- If the JammLite program does not launch or you receive an error message, contact APOC Technical Support and tell the support specialist you are unable to complete step **1.8** of this document.

Art: 731336-00B   Rev. Date: 13-Aug-13

1.9: In the JammLite utility, select the **i-STAT 300 Analyzer** within the Instrument dropdown menu.

Instrument

i-STAT 200 Analyzer
i-STAT 200 Analyzer
i-STAT 300 Analyzer
Blood Analysis Module
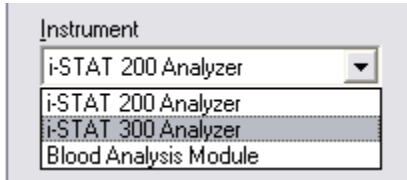
1.10: Select **TCP/IP** within the Port dropdown menu.

Port

TCP/IP
COM1
COM3
COM6
COM7
TCP/IP

1.11: Type the IP Address of the Network Downloader being used for the software update in the **IP Address** box.

IP Address

172.20.29.154
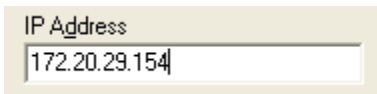
Note: the address used above is for example only.

1.12: Check that the **Application** and **CLEW** listings match those in the Product Update.

Click the **Update** button.

JammLite 4.3

Instrument
i-STAT 300 Analyzer
Port
TCP/IP
IP Address
172.20.29.154
Application
JAMS125A.BIN
CLEW
A16.CLW

✔ Update

⏏ Exit
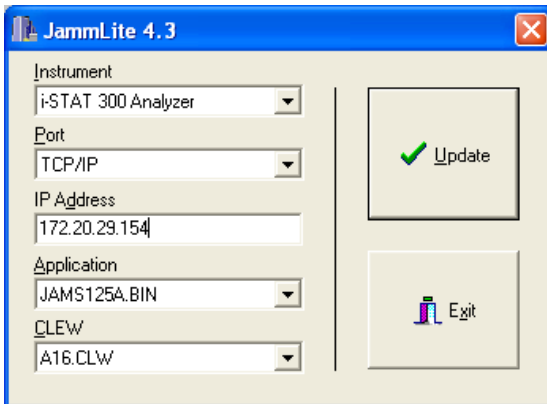
Note: Application and CLEW numbers are for example only.

1.13: Follow the onscreen instructions.

1) If an analyzer is already in the Downloader remove it.

2) Ensure the analyzer to be updated is off.

3) Place the analyzer in the Downloader.

Cancel

1.14: When the update is in progress, the following screen will appear:

An application update is in progress.

Please do not remove the analyzer from the Downloader.

Cancel

Programming application block 108 / 2055

The handheld will have 1's and 0's streaming across the screen signifying that it is receiving the software.

Do not move the handheld until the success screen is displayed.

The application update was successful.

The CLEW update was successful.

Close

1.15: Run the Electronic Simulator in the handheld. When the simulator finishes, PASS should be displayed.

Note: If PASS is not displayed, re-run the Electronic Simulator. If the repeated Electronic Simulator attempt fails, contact APOC Technical Support. For additional information on running the electronic simulator, see Section 14 of the i-STAT 1 System Manual.

Congratulations. **The process for updating the first i-STAT 1 Handheld is complete.**

Review the options below for additional instructions.

If there are no additional handhelds to update, the process is complete.

- Click the ❎ button in the upper right corner of the software screen.
- Close all other open boxes.
- Confirm all messages.

If there are additional handhelds to update via the same Network Downloader address:

- Click **Close.**
- Click **Update.**
- Repeat steps **1.12 through 1.15.**

If there are additional handhelds to update via a different Network Downloader address:

- Click **Close.**
- Repeat steps **1.11 through 1.15.**

If your facility uses Central Data Station:

- Proceed to and perform step **2.9**.

2. UPDATING THE i-STAT 1 HANDHELD USING THE CDS VERSION 5 CUSTOMIZATION WORKSPACE WITH A SERIAL OR NETWORK DOWNLOADER OR DOWNLOADER / RECHARGER, OR DRC-300

2.1: **Before starting the process, make sure all the required equipment / information is available:**

- **Computer with CDS Version 5 application**

- **Access to http://abbottpointofcare.com/softwareupdate**

- **i-STAT System Equipment**

    (1) i-STAT 1 handheld

    (2) Serial or Network Downloader, Downloader / Recharger, or DRC-300

    Note: These instructions assume that the Serial and Network Downloader types being used for the update process are already installed and in-use at the customer's facility.

    (3) Electronic Simulator

2.2: **Close all open programs on the computer including i-STAT Central Data Station.**

2.3: Navigate to www.abbottpointofcare.com/SoftwareUpdate.

2.4: Select Language from the drop-down menu.

2.5: If prompted, indicate the type of Data Management (if any) used with the i-STAT System.

Otherwise, proceed to Step **2.6**.

2.6: When prompted, click on the software file link and save file to:

- Desktop, or

- If you use CDS Version 5, save the file in the c:\bins directory. If the c:\bins directory does not exist, a bins folder will need to be created under the c: drive.

Close the "Download Complete" window.

2.7: Navigate to saved file location. Double click the software file "SUXXXXXX.exe".

2.8: Click Run. If a Command window opens prompting to overwrite, answer "Y" and then press Enter. Continue answering "Y" to all prompts that appear until the Command window closes.

2.9: **Update the CLEW and JAMS versions in the CDS Customization Workspace.**

- Open the Central Data Station application.

- Click on **Main → Open Administration Function → Customization**
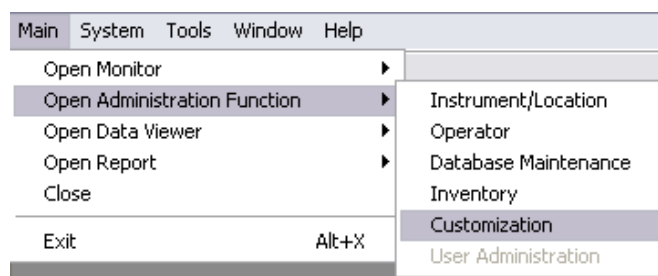
A Password box will then appear.

- Type in the Password and press Enter. The default password is **istat**. Note: Abbott Point of Care Inc. recommends changing the default password.

Note: If you are unable to open CDS Customization, please contact APOC Technical Support and indicate that your CDS Customization Password is unknown.

- If the **Enable Customization** box is not already checked, click the box next to this listing.

- Under the "Location-based customization profile:" section, make sure **Enable Updates** is checked for every location from which you wish to perform software updates on your i-STAT 1 Handhelds.

- Under the "Default customization profile:" column, double click on the **"i-STAT Analyzer CLEW"** button.
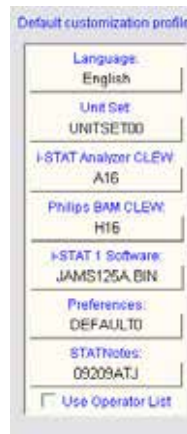
- The latest CLEW should be displayed in the CLEW window. Select the new version of **CLEW** and click **OK**.
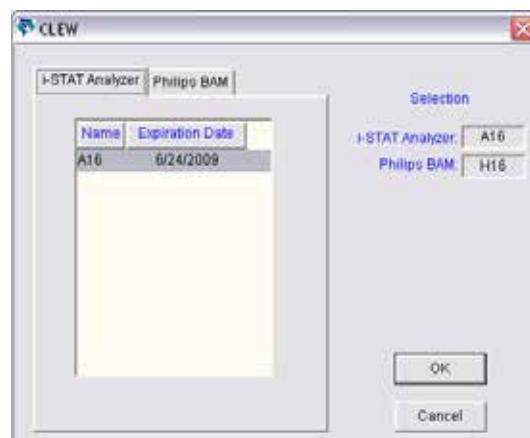
Click **Yes** for the confirmation message.

- If "Use Default Profile" is not checked beside any location-based customization profile, double click the box under the **"i-STAT Analyzer CLEW"** column.

- Click the new version of **CLEW**, and then click **OK**.

Click **Yes** for the confirmation message.

- Underneath the "Default customization profile:" column:

  - Double click on the "**i-STAT 1 Software:**" button.
  - Select the JAMS version that matches the Product Update.
  - Click **OK**.

2.10: Update the software in the i-STAT 1 handheld.

- Go to the location where the i-STAT 1 handheld you wish to update is located or contact someone at that location who can assist in updating the handheld(s).

- Press the **On/Off** button on the handheld.

- Press the **Menu** key to bring up the Administration Menu.

- Press **7 – Utility**. When prompted for a password, press **ENT**. If that did not work, a password is needed. Enter the password defined by your facility and press **ENT**. Note: Abbott Point of Care Inc. recommends changing the default password.

- From the Utility menu, press **3 – Receive Software**. A "Waiting to Send" message will appear on the handheld display.

- Place the handheld in the Downloader or Downloader/Recharger. **Do NOT move the handheld until step 2.11.** A **Communication in Progress** message will appear on the screen. After this disappears, the handheld display will stay blank for approximately 5-10 seconds.

- The handheld will then display 1's and 0's streaming across the screen signifying that it is receiving the software. Once the 1's and 0's disappear, the handheld display will again go blank for approximately 5-10 seconds.

- A **Waiting to Send** message following by a **Communication in Progress** message will then appear on the handheld display. After these messages disappear, the handheld display will go blank, and the update process is complete.

2.11: Run the Electronic Simulator in the handheld.
When the simulator finishes, PASS should be displayed.

Note: If PASS is not displayed, re-run the Electronic Simulator. If the repeated Electronic Simulator attempt fails, contact APOC Technical Support. For additional information on running the electronic simulator, see Section 14 of the i-STAT 1 System Manual.

Congratulations. The process for updating the first i-STAT 1 handheld is complete.

Review the options below for additional instructions.

- If there are no additional handhelds to update, the process is complete.

- If there are additional handhelds to update, return to step **2.10**.

3. UPDATING THE i-STAT 1 HANDHELD USING A SERIAL DOWNLOADER OR SERIALLY CONNECTED DRC-300 AND THE JammLite PROCESS FOR ACCOUNTS WITH RALS-Plus AND i-STAT/DE

3.1: **Before starting the process, make sure all the necessary required equipment is available.**

- Computer with:

    o   RALS-Plus IMS
    o   Applicable ports, depending on the type of downloader being used
    o   Access to http://abbottpointofcare.com/softwareupdate

- i-STAT System Equipment

    (1)   i-STAT 1 handheld
    (2)   Serial Downloader, Downloader / Recharger, or DRC-300

    Note: These instructions assume that the Serial Downloader types being used for the update process are already installed and in use at the customer's facility.

    (3)   All supplied downloader cables
    (4)   Electronic Simulator

3.2: Using the supplied downloader cables, connect the i-STAT 1 serial Downloader, Downloader/Recharger, or DRC-300 to an accessible port on the back of the computer, and connect the power supply to a wall outlet or power strip.

3.3: Close all open programs on the computer.

3.4: Disable the RALS remote connections.

- Right click on the red RRC dot in the lower right corner of the display next to the clock and go to "Administrator Settings."

- Enter the RRC Password of the Day. Call 877-627-7257 to obtain the password, or go to http://www.medicalautomation.com/RRC_Password.htm and type "richmond" as the key code. Note: Abbott Point of Care Inc. recommends changing the default password.

- Double click on "**COM1.**"
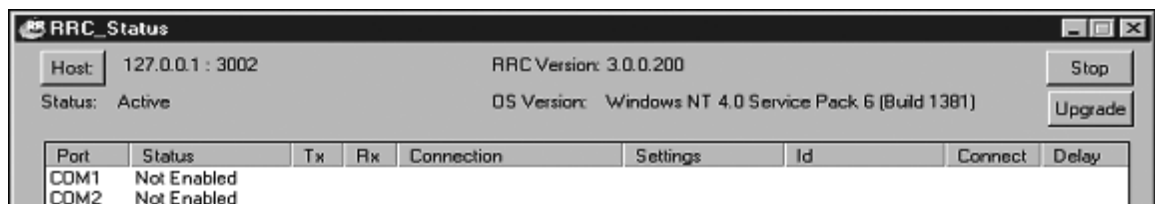
- Record "**<u>Host</u>**" and "**<u>ID</u>**" entry.

- Uncheck the "**<u>Enabled</u>**" box. Click **OK**.
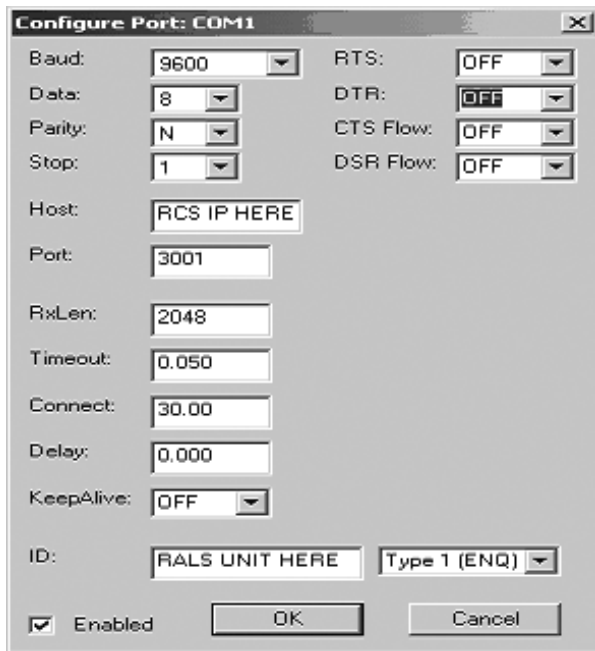
- If not enabled, minimize the window and proceed to the next step.

3.5: Navigate to <u>www.abbottpointofcare.com/SoftwareUpdate</u>.

- Select Language from the drop-down menu.

- Indicate the Data Management type and Version used with the i-STAT System.

- When prompted, click on the software file link and save file to Desktop.

- Close the "Download Complete" window.

- Navigate to Desktop. Double click the software file "SUXXXXXX.exe".

- Click Run. If a Command window opens prompting to overwrite, answer "Y" and then press Enter. Continue answering "Y" to all prompts that appear until the Command window closes.

3.6: Double click   📚 JAMMLITE.EXE .

- If the JammLite program does not launch or you receive an error message, contact APOC Technical Support and tell the support specialist you are unable to complete step **3.6** of this document.

3.7: In the JammLite utility, select the i-STAT 300 Analyzer within the Instrument drop-down menu.
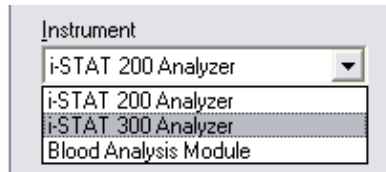
3.8: Make sure there is at least one port number listed under the Port Drop-Down List.
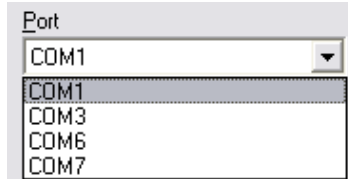
Note: If the Port drop-down list says "None." make certain the connection from the Serial Downloader to the computer is tight. Then reboot the computer and return to step **3.3.**
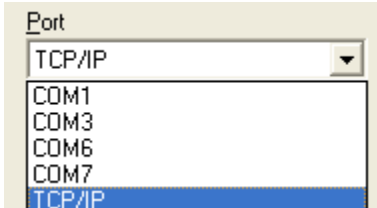
3.9: Check that the Application and CLEW listings match those in the Product Update for the current software release. If the update is for CLEW only, select **None** for Application.

3.10: Click on the "Update" button.
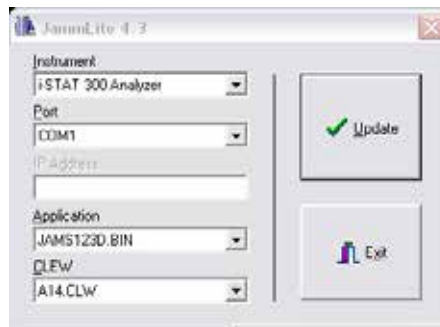
Note: Application and CLEW numbers are for example only.

3.11: Follow the onscreen instructions.

1) If an analyzer is already in the Downloader remove it.

2) Ensure the analyzer to be updated is off.

3) Place the analyzer in the Downloader.

3.12: When the update is in progress, the following screen will appear:

An application update is in progress.

Please do not remove the analyzer from
the Downloader.

Cancel

Programming application block 108 / 2055

The handheld will have 1's and 0's streaming across the screen signifying that it is receiving the software.

Do not move the handheld until the success screen is displayed.

The application update was successful.

The CLEW update was successful.

Close
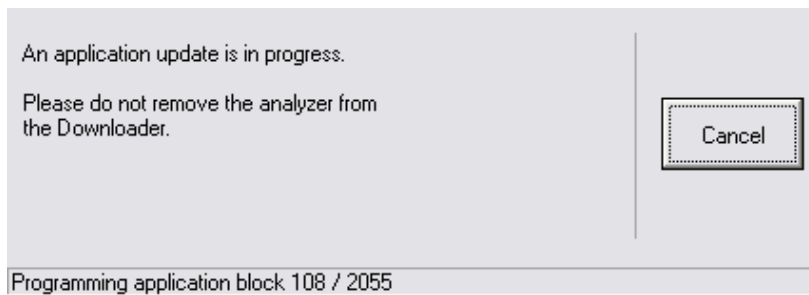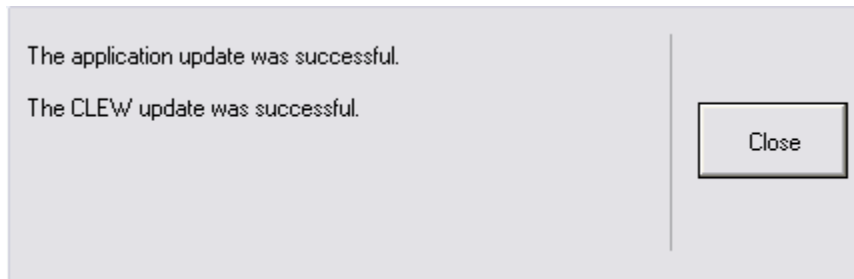
3.13: Run the Electronic Simulator in the handheld. When the simulator finishes, PASS should be displayed.

Note: If PASS is not displayed, re-run the Electronic Simulator. If the repeated Electronic Simulator attempt fails, contact APOC Technical Support. For additional information on running the electronic simulator, see Section 14 of the i-STAT 1 System Manual.

Congratulations. The process for updating the first i-STAT 1 handheld is complete.

If there are additional handhelds to be updated via JammLite:

- Click **Close.**
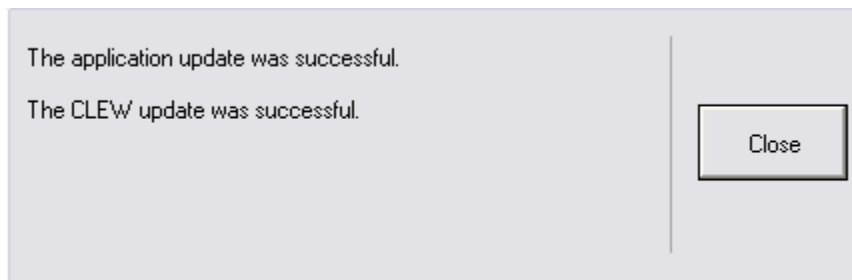- Repeat steps **3.10 through 3.13**.

If there are no additional handhelds to update, the process is complete.

- Click the button in the upper right corner of the software screen.
- Proceed to step **3.14** to restart the RRC if it was disabled in Step **3.4.**
- Proceed to step **3.14** to update the RALS-Plus i-STAT/DE with the latest CLEW and JAMS software files.

3.14: Restart the RALS remote connection.

- Maximize the RRC Status window.
- Double click on Com1.
- Check the "Enabled" box.
- Enter the recorded "Host" and "ID" entry from step **3.4.**
- Click "OK."

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3.15: Update the CLEW version in the Customization Workspace.

- Transfer the files.
    - ○ Access the main Customization Workspace page.
    - ○ Click **Update i-STAT/DE → Upload Update File.**
    - ○ Browse to desktop, click on ☐ XXX.CLW and click **Upload**.

        (Note: the XXX is the CLEW version that you are updating.)
    - ○ Click **Update i-STAT/DE → Upload Update File.**
    - ○ Browse to Desktop, click on ☐ JAMSXXXX.BIN and click **Upload.**

        (Note: the XXXX is the JAMS version that you are updating.)

- In the Customization Workspace, under the "Default customization profile:" column, click on the **"i-STAT Analyzer CLEW"** button.

    Note: Customization screens may vary depending upon the i-STAT/DE version in use.

- Check the box next to the new version of **CLEW** and click **OK**.

Answer OK to the question that appears.

- If "Uses Default" is not checked beside any Location-based customization profile, click the box under the "**i-STAT Analyzer CLEW**" column.

- Click the new version of **CLEW**, and then click **OK**.

Answer OK to the question that appears.

- Under the "Default Customization profile:" column, click on the **i-STAT 1 Software** drop-down list. Select the JAMS version that matches the Product Update and click **OK**.

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4. UPDATING THE i-STAT 1 HANDHELD USING THE i-STAT/DE CUSTOMIZATION WORKSPACE AND A NETWORK DOWNLOADER, DOWNLOADER/RECHARGER, or DRC-300

4.1: Before starting the process, make sure all the required equipment / information is available.

- **Computer which can access the Customization Workspace**

- **Access to http://abbottpointofcare.com/softwareupdate**

- **i-STAT System Equipment**

    (1) i-STAT 1 handheld

    (2) Network Downloader, Downloader/Recharger, or DRC-300

    Note: These instructions assume that the Network Downloader types being used for the update process are already installed and in use on the customer's network.

    (3) Electronic Simulator

4.2: Update the CLEW and JAMS versions in the Customization Workspace.

- Transfer the files.

    o Navigate to www.abbottpointofcare.com/SoftwareUpdate.

    o Select Language from the drop-down menu.

    o Indicate the type of Data Management and Version used with the i-STAT System.

    o When prompted, click on the software file link and save file to Desktop.

    o Close the "Download Complete" window.

    o Access the main Customization Workspace page.

    o Click **Update i-STAT/DE → Upload Update File**

    o Browse to Desktop, click on ▣ SUXXXXXX.EXE and click **Upload**. (Note: the XXXXXX is the JAMS and CLEW version that you are updating.) Immediately after uploading the CLEW/JAMS to the i-STAT/DE server, i-STAT/DE will unpack the files and make them available for use in the handheld's Customization Workspace.

4.3: Close Windows Explorer by clicking on the ❌ in the upper right corner.

4.4: Access the Customization Workspace.

- RALS-Plus Users:

    o From the RALS-Plus Application, pick i-STAT from the drop-down menu.
    o Click on **Device Customization.**

- PrecisionWeb Users:

    - Double click on the desktop shortcut or Internet Explorer Favorites for **i-STAT Customization**.

4.5: Update the CLEW and JAMS versions in the Customization Workspace.

- Under the "Default customization profile:" column, click on the "**i-STAT Analyzer CLEW**" button.

    Note: Customization screens may vary depending upon i-STAT/DE version in use.
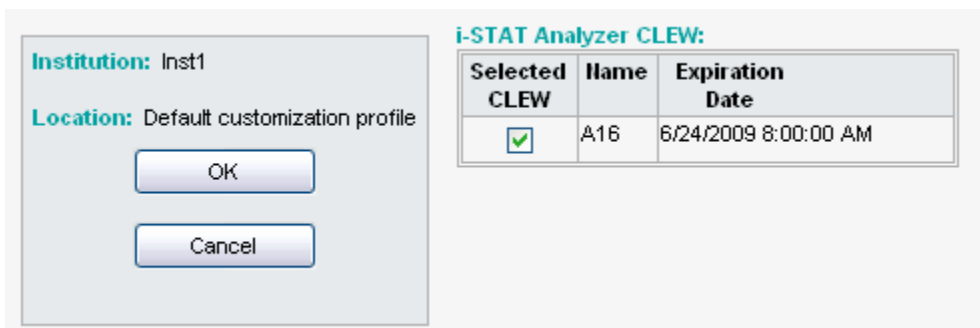
- Check the box next to the new version of **CLEW** and click **OK**.

    Answer OK to the question that appears.

- If "Uses Default" is not checked beside any Location-based customization profile, click the box under the "**i-STAT Analyzer CLEW**" column.

Location-based customization profiles:

Location	Enabled	Uses Default	Update CLEW	i-STAT Analyzer CLEW	Philips BAM CLEW	Preferences	STATNotes	☐
ER	☐	☑	☑	A16	[None]	DEFAULT0	CHART0	☐
ICU	☐	☐	☑	A16	[None]	DEFAULT0	CHART0	☐
Lab	☐	☑	☑	A16	[None]	DEFAULT0	CHART0	☐
OR	☐	☐	☑	A16	[None]	DEFAULT0	CHART0	☐

- Click the new version of **CLEW**, and then click **OK**.
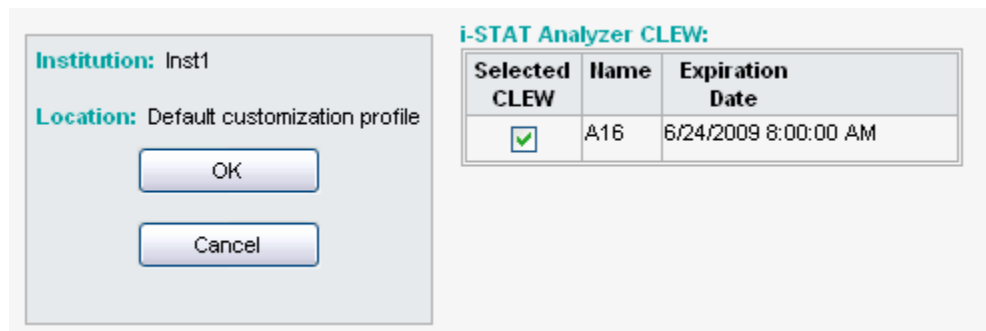
Answer OK to the question that appears.

- Under the "Default Customization profile:" column, click on the **i-STAT 1 Software** drop-down list. Select the JAMS version that matches the Product Update and click **OK**.

4.6: Enable Customization.

- If the **Enable Customization** box is not already checked, click the box next to this listing.

- Under the "Location-based customization profile:" section, make sure **Enabled** is checked for every location from which you wish to perform software updates on your i-STAT 1 handhelds.

4.7: Update the software in the i-STAT 1 handheld.

- Go to the location where the i-STAT 1 handheld(s) you wish to update are located or contact someone at that location who can assist in updating the handheld(s).

- Press the **On/Off** button on the handheld.

- Press the **Menu** key to bring up the Administration Menu.

- Press **7 – Utility**. When prompted for a password, press **ENT**. If that did not work, a password is needed. Enter the password defined by your facility and press **ENT**. Note: Abbott Point of Care Inc. recommends changing the default password.

- From the Utility menu, press **3 – Receive Software**. A "Waiting to Send" message will appear on the handheld display.

- Place the handheld in the downloader or downloader / recharger. **Do NOT move the handheld until step 4.8.** A **Communication in Progress** message will appear on the screen. After this disappears, the handheld display will stay blank for approximately 5-10 seconds.

- The handheld will then display 1's and 0's streaming across the screen signifying that it is receiving the software. Once the 1's and 0's disappear, the handheld display will again go blank for approximately 5-10 seconds.

- A **Waiting to Send** message following by a **Communication in Progress** message will then appear on the handheld display. After these messages disappear, the handheld display will go blank, and the update process is complete.

4.8: Run the Electronic Simulator in the handheld. When the simulator finishes, PASS should be displayed.

Note: If PASS is not displayed, re-run the Electronic Simulator. If the repeated Electronic Simulator attempt fails, contact APOC Technical Support. For additional information on running the electronic simulator, see Section 14 of the i-STAT 1 System Manual.

Congratulations. The process for updating the first i-STAT 1 handheld is complete.

Review the options below for additional instructions.

- If there are no additional handhelds to update, the process is complete.

- If there are additional handhelds to update, return to step **4.7**.

Introduction   When the analyzer detects a potential or real problem before the test cycle is initiated or at any time during the test cycle, a Quality Check Code number, the type of problem and the next step to be taken will be displayed. The Code number may be helpful to a technical support representative if a problem cannot be resolved. If a problem cannot be resolved by the procedures described in this section, refer to Support Services information in the Troubleshooting section.

Note: Troubleshooting for results and quality tests are covered in those sections of this manual.

Note: The Technical Bulletin "Analyzer Coded Messages" included in this manual lists the Quality Check Code numbers as well as additional troubleshooting details

Caution   DO NOT OPEN THE ANALYZER, or any other i-STAT product, or perform any unauthorized procedures. Opening any i-STAT product, including analyzer, Electronic Simulator, printer or communication device, in attempt to repair it or resolve a problem may cause erroneous results. If the troubleshooting procedures found in this manual or requested by an i-STAT support specialist do not resolve the problem, the product must be returned to i-STAT for repair.

Information Needed   Have the following pertinent information available for review with the representative:

- Description of problem

- When problem first occurred and what has been done so far to resolve the problem

- Serial number of component(s)

- Displayed message and code number

- Frequency of problem

- Software version

- Environmental conditions

- Result of last Electronic Simulator test

- Battery voltage from Analyzer Status page

STARTUP MESSAGES

Overview   Whenever the analyzer is turned on using the On/Off key, the analyzer performs self-checks. If a condition that should be corrected in the near future, but that will not affect results is detected, a warning is displayed. The operator presses the 1 key to continue with testing. If the analyzer has been customized to disable testing under any of these conditions, the condition must be corrected and the analyzer turned off and back on before testing will be enabled.

Message on Display	Explanation	How to Respond
Electronic Simulator Test Required	Analyzer customized to alert the operator that a scheduled simulator test is due.	Insert the external Electronic Simulator at the earliest convenient time.
Stored Memory Low	Memory space for 50 unsent test records available before the "Stored Memory Full" message is displayed.	Place the analyzer in a Downloader.
Stored Memory Full	The analyzer is customized to alert the operator that the memory for unsent records is full. If the operator does not transmit the test records to the Point-of-Care Central Workstation, the analyzer will either block further testing or will overwrite oldest records depending on how the analyzer is customized.	Place the analyzer in a Downloader.
Upload Required	The analyzer is customized to alert the operator that a scheduled transmission of test records to the Central Data Station is due.	Place the analyzer in a Downloader.
Battery Low	Battery voltage has dropped to 7.4 volts. There is sufficient power to test a few more cartridges, the number depending mainly on the types of cartridges in use. Under this condition, a flashing battery icon will also appear on the result page, the Test Menu screen, and the Administration Menu screen.	Change the disposable lithium batteries or recharge the rechargeable battery.
CLEW Expiring, Update Required	Message appears 15 days before the software expires.	Update the analyzer before the expiration date.

TEST CYCLE MESSAGES AND QUALITY CHECK CODES

Overview
If a problem is detected during a testing cycle, the cycle will be stopped and a message will identify the problem and indicate the next step to be taken. If the problem causes testing to be disabled, the problem must be corrected and the analyzer must be turned off and back on before testing will be enabled.

Environmental Conditions
The following messages usually indicate a condition related to the environment or the state of the analyzer. These conditions are usually benign and go away after the the offending condition is corrected.

Message on Display	Cause	Action
Date Invalid, Check Clock	The analyzer will not allow a date that precedes or exceeds the six months lifetime of the CLEW software.	Press **Menu** once to go to the Test Menu and then again to go to the Administration Menu. Press 5 to go to the Set Clock screen and correct the date.
Dead Batteries, Replace Batteries	There is insufficient battery power to complete a test cycle.	Change the disposable lithium batteries or recharge the rechargeable battery.
Temperature Out of Range, Check Status Page	The analyzer makes a temperature measurement before initiating a test cycle.	Check the temperature reading on the Analyzer Status screen (under the Administration Menu). If below the operating range, move to a warmer area. If above the operating range, move to a cooler area. Allow time for the analyzer to equilibrate to the new temperature. Check the Analyzer Status screen periodically.
Invalid or Expired CLEW	The software has become corrupt or has expired. The Product Update for each software update includes the expiration date.	Verify that the date in the analyzer is correct. Change the software if expired. Update the software again if not expired. If the message is displayed again, refer to Support Services information at the end of this section.
Analyzer Interrupted, Use Another Cartridge	The analyzer detected that the last cartridge run was not completed. This can happen if battery voltage is low, or if batteries were removed or making poor contact while a cartridge was still in the analyzer.	Check that the battery pack is inserted properly. Turn the analyzer on and check for the Low Battery message; replace or recharge if needed.

Error in Cartridge or Fluid Movement
The following conditions usually indicate an error condition relating in some way to the cartridge or fluid movement within a cartridge. These conditions can be operator or sample related. In most cases a new cartridge must be used. If a condition persists, especially if isolated to one analyzer, there may be an analyzer problem.

Message on Display	Cause	Action
Cartridge Error Use Another Cartridge	These codes can all be caused by a variety of reasons including sample-related problems, users, cartridges or analyzers. Single or sporadic errors are most likely a sample-related problem (an interferent), an aberrant cartridge, or a user-induced situation such as touching cartridge contacts, pressing on center of cartridge or bubbles in the sample ("frothy" samples).	Use another cartridge. If the same code repeats more than twice, there may be an analyzer problem. Try another analyzer if available.
Cartridge Preburst Use Another Cartridge	This code indicates that the analyzer detected fluid on the sensors before it should have. Possible causes: • Cartridges may have been frozen. • Calibrant pack, if applicable, may have been burst by operator exerting too much pressure on the center of the cartridge.	Try another cartridge. Make sure that the cartridges were not frozen.
Unable to Position Sample Use Another Cartridge	The analyzer did not detect movement of sample across the sensors. This could be due to: • not closing the snap closure on the cartridge. • a clot in the sample preventing movement of the sample. • an aberrant cartridge.	Use another cartridge.
Sample Positioned Short of Fill Mark Use Another Cartridge	The cartridge was under-filled.	The sample must reach the fill mark. Try another cartridge.
Sample Positioned Beyond Fill Mark Use Another Cartridge	The cartridge was overfilled.	The sample was past the fill mark. Try another cartridge.

Error in Cartridge or Fluid Movement (continued)

Message on Display	Cause	Action
Insufficient Sample Use Another Cartridge	This is most likely due to insufficient sample in the sample well of the cartridge, but can also be caused by bubbles in the sample.	Try another cartridge.
Cartridge Not Inserted Properly Reinsert Cartridge	The code indicates the cartridge or external Electronic Simulator may not be pushed in all the way.	Reinsert the cartridge or Electronic Simulator. If problem is recurrent and/or the user is certain the cartridge or Simulator is properly inserted, it may indicate an instrument problem. Refer to Support Services.
Test Cancelled by Operator	No response to mandatory prompt before analyzer time out.	No action required. Training may be required if a particular operator has a high rate of cancelled tests.

Electrical or Mechanical Failures

The following conditions are related to electronic or mechanical failures in the analyzer.

Message on Display	Cause	Action
Analyzer Error Use Electronic Simulator	The analyzer usually recovers from these errors when the Electronic Simulator is run. This error can occur if the cartridge or Electronic Simulator was "angled" when inserted.	Push cartridge or Simulator straight through the cartridge port. This error can also occur if the Electronic Simulator is malfunctioning (has it been dropped?). Try another Simulator. If the analyzer passes the Electronic Simulator check, continue to use it. If not, or if the Quality Check Code is recurrent, the analyzer may need repair.
Analyzer Error See Manual	These are mechanical or electronic failures from which the analyzer may not be able to recover.	Use an external Electronic Simulator twice and use a cartridge with sample or control solution. If an error condition occurs, refer to Support Services. If not, continue to use the analyzer.
Cartridge Type Not Recognized Use Another Cartridge	This error could be due to use of a cartridge type that is not compatible with the version of software in the analyzer.	If this is a new cartridge type being used, update the software. If the cartridge type has been used before, check to see if the cartridges have expired. Otherwise, an analyzer problem is indicated and the analyzer may need repair.
Internal Simulator Failure	This error can occur if poor contact is made between the handheld pins and the contact pads of the cartridge.	**Lockout Enabled:** Immediately rerun the cartridge in the same handheld. If the simulator test fails again, rerun the cartridge is another handheld. Note: the cartridge should not be run if there is more than a three minute delay from the time it was filled. Verify the failed handheld using an external electronic simulator. **Lockout Not Enabled:** Immediately rerun the cartridge in another handheld. Note: the cartridge should not be run if there is more than a three minute delay from the time it was filled. Verify the failed handheld using an external electronic simulator.

No Display

Symptom	Possible Cause	Action
The display screen remains blank, either after a cartridge has been properly inserted or after the On/Off key has been pressed.	Batteries dead. Keypad not responding. Internal Start switch broken.	Change or recharge batteries. If this does not fix the problem, reinstall the current software in the analyzer. If the problem persists, the analyzer should be returned for repair.
		If using the analyzer recharging function of the i-STAT 1 Downloader/Recharger, ensure that the Downloader/Recharger is working as intended. If experiencing an issue, contact your support representative and use disposable batteries for continued use of the analyzer.

"Cartridge Locked" Not Removed

Symptom	Possible Cause	Action
Normally the analyzer will reset and release the cartridge after the testing cycle is completed. If the analyzer cannot reset, the "Cartridge Locked" message will remain on the screen.	Dead batteries. Mechanical problem.	Wait until the analyzer turns off or turn the analyzer off. Then turn the analyzer on. If it can reset, it will release the cartridge and remove the "Cartridge Locked" message. If the cartridge is not released, change or recharge the battery and turn the analyzer on.
		If the "Cartridge Locked" message does not disappear, do not attempt to remove the cartridge and refer to Support Services.

Art: 714381-00J Rev. Date: 11-Mar-14

i-STAT®
TECHNICAL BULLETIN

ANALYZER CODED MESSAGES

From the time it powers up until the time it powers down, the i-STAT® Analyzer performs numerous quality checks. The failure of any quality check causes the analyzer to halt the test cycle and display a "cause", an "action" message, and a code.

The Cause Message:
This message describes the likely cause of the failed quality check. For example, when an overfilled cartridge is detected, the analyzer will display "Sample Positioned Beyond Fill Mark".

The Action Message:
This message indicates the appropriate action. For example, if it is likely the quality check will fail again the next time the analyzer is used, the instruction "Use Electronic Simulator" will be displayed. If the problem is related to an operator or cartridge, the instruction "Use Another Cartridge" will be displayed.

The Cause Code:
This is a numeric code associated with the failed quality check. Since multiple codes can be associated with a single cause message, this is essential information when contacting i-STAT Technical Services or your local support organization for further assistance. The codes are stored in the analyzer's memory along with other test records and are transmitted to the Central Data Station. The code list can be viewed and printed.

Codes 1-15 and 95 usually indicate a condition related to the environment or the state of the analyzer. These conditions are usually benign and go away after the next cartridge or Electronic Simulator is inserted, or after the offending condition is corrected.

Code Number	Cause/Action Message on Display	Explanation
1	**Dead Batteries** / Replace Batteries	There is insufficient battery power to complete the testing cycle. Replace the disposable lithium batteries in the analyzer or recharge the rechargeable batteries.
		If you are experiencing this code frequently and use disposable batteries with the i-STAT 1 Analyzer, you may want to consider the rechargeable battery system available with the i-STAT 1 Analyzer.

Code Number	Cause/Action Message on Display	Explanation
2	**Temperature Out of Range** / Check Status Page	The analyzer is recording a temperature outside its operating range. Move the analyzer to an area within the operating temperature of the test being performed and allow the analyzer to come to the new room temperature. Check the analyzer's temperature reading on the Status Page.
4, 8	**Analyzer Interrupted** / Use Another Cartridge	The analyzer has detected that the last test cycle was not completed. This can happen if the batteries were removed or were making poor contact while a cartridge was still in the analyzer. Batteries that are too short will not make proper contact. Check that the batteries are inserted properly and seated well in the analyzer; check the battery voltage on the analyzer's Status Page and replace batteries if low. NOTE: Patient results displayed before this code are valid.
11	**Date Invalid** / Check Clock on Status Page	If the date in the real time clock precedes the release date programmed into the application software, code 11 is triggered. Check the date on the real time clock.
		The accuracy of the clock is checked at the beginning of a coagulation test. If the clock is inaccurate, Code 11 is triggered.
12	**Invalid or Expired CLEW** / See Manual	The CLEW standardization has expired. Download a valid CLEW.
		The date on the real time clock exceeds the expiration date of the CLEW software. Check the date on the real time clock.
13	**Invalid or Expired CLEW** / See Manual	The CLEW is corrupt or not compatible with the application software (JAMS), or there is no CLEW in the analyzer. Download a valid CLEW. If this code occurs after a software upgrade and the customization application is enabled in the CDS, change the CLEW version in the Customization Profile to the latest version and re-transmit the profile to the analyzer.
14	**Analyzer Error** / See Manual	Customization profile is corrupted. Download analyzer to the data manager. If code 14 reoccurs, contact i-STAT Technical Services or your local support organization for further assistance.
15	**Barcode Does Not Match Cartridge Type**	The barcode scanned by the user does not match the immunoassay cartridge type indicated by the identification chip in the cartridge. The user should run another cartridge, being careful to scan the barcode from the portion pack of the specific cartridge type being run on the analyzer.
95	**Test Cancelled by Operator**	This message will appear in the stored test records on the i-STAT 1 Analyzer if the analyzer powers down before mandatory information was entered.

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The following codes are associated with the cartridge or fluid movement within a cartridge. These conditions can be operator or sample related. In most cases, a new cartridge must be used. If a condition persists, especially if isolated to one analyzer, there may an analyzer problem.

Code Number	Cause/Action Message on Display	Explanation
19	**No Clot Detected** / See Manual	During the PT/INR cycle, no clot was detected. Run another cartridge. If code 19 reappears, run the sample on an alternate methodology.
22, 25	**Cartridge Error** / Use Another Cartridge	These codes occur only for coagulation cartridges if the mixing of the sample and reagent is compromised. This can be caused by an insufficient or clotted sample, or by air bubbles in the sample.
24	**Cartridge Error** / Use Another Cartridge	The electrical resistance of the calibrant fluid (Rcal) used to verify the electrolyte concentration is out of specification. This could occur if the calibrant pack was ruptured well before the test allowing evaporation to result in a higher electrolyte concentration.

Besides the electrolyte concentration, the Rcal is also affected by the temperature and the height and width of the fluid segment over the conductometric sensor. The analyzer accounts for the temperature, but the height and width of the fluid segment can vary from cartridge lot to cartridge lot. The analyzer has been programmed to compensate for these lot-to-lot differences by maintaining a running average of the Rcal values measured from the most recent cartridge runs. Occasionally, the difference between the Rcal values for two cartridge lots is large enough to cause the introduction of a new lot to trigger code 24 on the first few cartridge runs. The Code 24 errors should disappear as the running average adjusts. However, if code 24 persists after more than 3 cartridge runs on each analyzer, contact i-STAT Technical Services or your local support organization. |
| 26 | **Cartridge Error** / Use Another Cartridge | This code occurs if there was a coagulation specific quality check failure: premature substrate activation, abnormally low levels of substrate, or invalid fluid motion. |
| 20, 27-29, 32, 33, 40, 41, 45, 87 | **Cartridge Error** / Use Another Cartridge | These codes identify problems with the cartridge such as: calibrant fluid arriving too soon, too late, or not at all, or noise in the calibrant fluid signals. Codes 20, 27, 41, and 87 can be caused by poor contact that can sometimes be corrected by conditioning the pins in the analyzer using the ceramic conditioning cartridge. The specific conditioning procedure is described at the end of this bulletin.

The rate of quality check code 45 can be elevated when cartridges are run without allowing sufficient time for the cartridges to equilibrate to room temperature. To minimize the number of quality check codes, review i-STAT cartridge storage conditions and allow sufficient time for refrigerated cartridges to equilibrate to room temperature. |
| 42, 43 | **Cartridge Error** / Use Another Cartridge | These codes indicate that the conductometric sensor (code 42) or the amperometric sensor (code 43) was out of specification. This could be caused by a pre-burst calibrant pack, dirty cartridge contact pads, or a dirty connector in the analyzer. |

Code Number	Cause/Action Message on Display	Explanation
79-81	**Cartridge Error** / Use Another Cartridge	Bad contact between the thermal probes in the analyzer and the metalization on the back of the chips in the cartridge trigger these codes. Causes are: poor metalization of the chips, dirt on the metalization, or bent or broken thermal probes in the analyzer.
21	**Cartridge Preburst** / Use Another Cartridge	This code indicates that the analyzer detected fluid on the sensors before it should have. Possible causes: mishandling of cartridges (putting pressure in the center of the cartridge), poor storage conditions of cartridges (frozen), or rerunning used cartridges.
31, 34, 44	**Unable to Position Sample** / Use Another Cartridge	The analyzer did not detect movement of sample across the sensors. This could be due to a clot in the sample (especially in neonates), to not closing the snap closure on the cartridge, or to an aberrant cartridge.
35, 36	**Sample Positioned Short of Fill Mark** / Use Another Cartridge	The cartridge was underfilled. The sample must reach the fill mark. Try another cartridge.
30, 37	**Sample Positioned Beyond Fill Mark** / Use Another Cartridge	The cartridge was overfilled. The sample was past the fill mark. Try another cartridge.
38, 39	**Insufficient Sample** / Use Another Cartridge	This is most likely due to insufficient sample in the sample well of the cartridge, but can also be caused by bubbles in the sample. Try another cartridge and ensure sufficient sample is in the sample well.
46	**Cartridge Error** / Use Another Cartridge	The analyzer did not detect movement of sample across the sensors. This could be due to a clot in the sample (especially in neonates), to not closing the snap closure on the cartridge, or to an aberrant cartridge.
47	**Cartridge Not Inserted Properly** / Reinsert Cartridge	This code indicates the cartridge or Electronic Simulator may not be pushed in all the way. Reinsert the cartridge or Electronic Simulator. If the problem persists and/or the user is certain the cartridge or Simulator is properly inserted, it may indicate an analyzer problem. Contact i-STAT Technical Services or your local support organization for further assistance.
48	**Analyzer Error** / See Manual	This code indicates the cartridge or Electronic Simulator may have been "cocked" when inserted. Push the cartridge or Simulator straight through the cartridge port. If the problem persists, and the user is certain the cartridge or Simulator is properly inserted, it may indicate an analyzer problem. Contact i-STAT Technical Services or your local support organization for further assistance.

Code Number	Cause/Action Message on Display	Explanation
49	**Poor Contact Detected** / See Manual	The system detected a contact problem with one of the connector pins while reading the identification chip in the immunoassay cartridge. This can sometimes be corrected by conditioning the pins in the analyzer using the ceramic conditioning cartridge. The specific conditioning procedure is described at the end of this bulletin. **Note:** If you do not have a ceramic conditioning cartridge, please contact i-STAT Technical Support at 1-800-366-8020, option 1.

The following conditions are related to electronic or mechanical failures in the analyzer.

Code Number	Cause/Action Message on Display	Explanation
50	**Analyzer Error** / Use Electronic Simulator	The motor has moved too far. Running a simulator may not detect this problem. Run the simulator and if the analyzer passes, run a cartridge to see if the code reoccurs. If not, continue to use the analyzer. If the code reoccurs, contact i-STAT Technical Services or your local support organization for further assistance. If testing immunoassay cartridges on an i-STAT 1 Analyzer, this code can be related to poor electrical connection between the i-STAT 1 Analyzer and the cartridge. This can sometimes be corrected by conditioning the pins in the analyzer using the ceramic conditioning cartridge. The specific conditioning procedure is described at the end of this bulletin. **Note:** If you do not have a ceramic conditioning cartridge, please contact i-STAT Technical Support at 1-800-366-8020, option 1. Codes 126 and 128 are sometimes related to electrical connection as well. If you experience multiple occurrences of these 3 codes (50, 126, and 128) in a short period of time, consider returning the analyzer for servicing and replacement The presence of sample bubbles when running immunoassay cartridges may, under some circumstances, also elicit this code.
51	**Analyzer Error** / Use Electronic Simulator	The motor moved for too long. Run a simulator. If the error occurred while running an ACT cartridge, also run a cartridge. If the code does not reoccur, continue to use the analyzer. Under some conditions, a low battery will cause this error instead of code 1. Try fresh batteries. If the code reoccurs, contact i-STAT Technical Services or your local support organization for further assistance.
52	**Analyzer Error** / Use Electronic Simulator	The motor stalled while moving. Run a simulator. If the error occurred while running an ACT cartridge, also run a cartridge. If the code does not reoccur, continue to use the analyzer. If the code reoccurs, contact i-STAT Technical Services or your local support organization for further assistance.

Code Number	Cause/Action Message on Display	Explanation
58-62	**Analyzer Error** / Use Electronic Simulator	The analyzer usually recovers from these error conditions. These error conditions can be detected by the Electronic Simulator. If the analyzer passes the Electronic Simulator test, continue to use it. If not, check the battery voltage and check the analyzer with another simulator to rule out a simulator problem. If the code persists, contact i-STAT Technical Services or your local support organization for further assistance.
23, 53, 55-57, 63, 65-68, 72-74, 82, 83-85, 86, 89-94, 96, 97	**Analyzer Error** / See Manual	These are mechanical or electronic failures from which the analyzer may not be able to recover.
		Code 23 may be caused by poor contact between the analyzer pins and the cartridge chip. This can sometimes be corrected by conditioning the pins in the analyzer using the ceramic conditioning cartridge. The specific conditioning procedure is described at the end of this bulletin.
		Codes 82 and 92 typically indicate a problem with the pressure transducers in the analyzer. If these codes persist, contact i-STAT Technical Services or your local support organization for further assistance.
		Codes 83 and 84 indicate an underlying hardware failure in the i-STAT 1 Wireless Analyzer. If these codes persist, contact i-STAT Technical Support or your local support organization for further assistance.
		The rate of quality check code 55 can be elevated when cartridges are run without allowing sufficient time for the cartridges to equilibrate to room temperature. To minimize the number of quality check codes, review i-STAT cartridge storage conditions and allow sufficient time for refrigerated cartridges to equilibrate to room temperature.
		Code 56 occurs when the analyzer detects noise on the thermal circuit. The noise may be the result of electronic interference. If this code occurs, the analyzer should be moved to a different location away from potential sources of interference. If the code persists in the new area, the analyzer should be returned.
		Code 86 can occur when an i-STAT Analyzer is stored in an i-STAT Downloader/Recharger without adequate ventilation. This problem can usually be resolved by moving the Downloader/Recharger to an open location which is free of obstructions and external heat sources such as heater vents or other electronic equipment. If this code persists, or if code 86 occurs with the i-STAT 1 Analyzer without a Downloader/Recharger, contact i-STAT Technical Services or your local support organization for further assistance.
		For other codes, run the Electronic Simulator twice, then run a cartridge with a sample. If the analyzer passes the simulator check and a quality check does not occur with the sample run, continue to use the analyzer. If the analyzer does not pass the simulator check and/or a quality code occurs with the sample run, contact i-STAT Technical Services or your local support organization for further assistance.

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Code Number	Cause/Action Message on Display	Explanation
69	**Cartridge Type Not Recognized** / Use Another Cartridge	This code could be due to use of a cartridge type that is not compatible with the version of software in the analyzer, or the use of expired cartridges. Check the cartridge expiration date on the cartridge box or pouch. If the cartridges have not expired, and if a new cartridge type is being run, contact i-STAT Technical Services or your local support organization for a software update.
		When running coagulation cartridges, Code 69 may be caused by poor contact between the analyzer pins and the cartridge chip. This can sometimes be corrected by conditioning the pins in the analyzer using the ceramic conditioning cartridge. The specific conditioning procedure is described at the end of this bulletin.
		This code will be displayed if incorrect information is entered in response to the prompt "Scan Cartridge Lot Number".
		The instrument expects the barcode on the individual cartridge pouch to be scanned.
		The instrument will not accept keypad entries of the cartridge lot number nor a scan of the barcode on the cartridge box.
		This condition may be due to an aberrant cartridge. However, if the condition occurs repeatedly on one analyzer, the analyzer may need repair. Contact i-STAT Technical Services or your local support organization for further assistance.

Codes in the range of 120 to 138 and 140 to 151 indicate a failure during an immuno or barcoded pouch cartridge cycle. In most cases, the cartridge is spent and another cartridge must be used.

Code Number	Cause/Action Message on Display	Explanation
120-122, 124, 125, 133, 144, 148	**Cartridge Error /** Use Another Cartridge	These codes indicate a problem with the movement of the analysis fluid during the cartridge run. Try another cartridge.
123	**Cartridge Error /** Use Another Cartridge	The quality control during the cartridge run failed to verify the presence of active immuno reagents. Try another cartridge.
126	**Cartridge Error /** Use Another Cartridge	The quality control during the cartridge run failed to verify the integrity of the analysis fluid. However, this code can also be related to poor electrical connection between the i-STAT 1 Analyzer and the cartridge. This can sometimes be corrected by conditioning the pins in the analyzer using the ceramic conditioning cartridge. The specific conditioning procedure is described at the end of this bulletin.
		Note: If you do not have a ceramic conditioning cartridge, please contact i-STAT Technical Support at 1-800-366-8020, option 1.
		Codes 50 and 128 are sometimes related to electrical connection as well. If you experience multiple occurrences of these 3 codes (50, 126, and 128) in a short period of time, consider returning the analyzer for replacement.
127	**Cartridge Error /** Use Another Cartridge	A wet sensor was detected before the initial sample movement. Possible overfilled or used cartridge. Try another cartridge.

Code Number	Cause/Action Message on Display	Explanation
128, 131, 132, 134, 135 - 138	**Cartridge Error /** Use Another Cartridge	These codes are most often related to poor filling of an immunoassay cartridge, the presence of sample bubbles, or the abrupt insertion of a cartridge into the analyzer. **Guidelines for proper filling:** 1. **Discard** (always) 1 drop from delivery device to clear unseen bubbles. 2. **Hang** single drop slightly larger than round target well. 3. **Touch** 1 drop (only) to round target well allowing cartridge to draw sample in. 4. **Confirm** sample volume lines up with top of fill mark. 5. **Close** cartridge. **Guidelines for cartridge insertion:** 1. After closing the cartridge, grasp the cartridge for insertion. • Original thumbwell design: grasp the closure between your thumb and first finger. There is a recess for your thumb on the closure. • Large thumbwell cartridge: grasp the thumbwell between your thumb and first finger. 2. Guide the cartridge into the analyzer gently, until a soft click is heard.
129, 142, 143	**Cartridge Error /** Use Another Cartridge	The analyzer detected analysis fluid mixed with the sample. Try another cartridge.
130	**Cartridge Error /** Use Another Cartridge	The analyzer detected an air bubble in the sample segment. Try another cartridge.
140	**Lot Expired**	The analyzer detected an expired cartridge lot. Check the expiration date and repeat the test using a non-expired cartridge lot.
141	**Test Canceled by Operator**	This code will be displayed if the cartridge barcode is not scanned within 60 seconds of cartridge insertion. The correct barcode to scan is the barcode on the cartridge portion pack, not the one on the cartridge box. An example of the portion pack barcode is found in the table listing for code 69 above.
145	**Cartridge Error /** Use Another Cartridge	The analyzer failed to detect fluid arrival upon the initial sample push. This may be caused by a(n): • cartridge leak. • failure to close the cartridge completely. Ensure that the closure is fully engaged before inserting the cartridge into the analyzer. • underfilled cartridge. Once a single drop of sample is touched to the target well, immunoassay cartridges will fill automatically by wicking the sample at a fixed speed. Trying to inject the sample into the cartridge or adding more sample to the target well will not make the cartridge fill faster. Wait for the sample to reach the fill mark and then close the cartridge.
146	**Cartridge Error /** Use Another Cartridge	Overfilled cartridge. Repeat the test.

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Code Number	Cause/Action Message on Display	Explanation
147	**Analyzer Error /** See Manual	In order to run an immunoassay cartridge, the i-STAT 1 Analyzer must bear the symbol:
149 - 151	**Cartridge Error** / Use Another Cartridge	The analyzer detected an atypical data stream from the cartridge. Try another cartridge. For BNP, if code 150 is encountered when running a whole blood sample, it is recommended that the sample be centrifuged and the test be repeated with the resulting plasma.

The following conditions are related to the Electronic Simulator

Code	Explanation	How to Respond
Numerical Code	See under Analyzer Coded Messages.	See under Analyzer Coded Messages.
L	Potentiometric channel out of limits. Can occur if moisture collects on the contact pins inside the analyzer when the analyzer is subjected to ambient temperature change.	Contact i-STAT Technical Services or your local support organization for further assistance.
G	Amperometric channel out of limits. Can occur if external simulator not inserted straight.	Contact i-STAT Technical Services or your local support organization for further assistance.
R, r	Resistance reading on conductometric channel out of limits.	Contact i-STAT Technical Services or your local support organization for further assistance.
t	Thermal probe failure.	Contact i-STAT Technical Services or your local support organization for further assistance.
B	Potentiometric channel out of limits.	Contact i-STAT Technical Services or your local support organization for further assistance.

NOTE: Any time repetitive codes occur which cannot be addressed or corrected through training, contact i-STAT Technical Services or your local support organization for further assistance.

PROCEDURE FOR USING AN i-STAT CERAMIC CONDITIONING CARTRIDGE (CCC) FOR ANALYZER PIN CONDITIONING

Step Number	Explanation
1. Run an external Electronic Simulator.	If the analyzer is configured with the internal Electronic Simulator enabled, run an external Electronic Simulator. Running the external Electronic Simulator ensures the internal Simulator cycle will not execute during the pin conditioning process, which could lead to the premature termination of the process.
2. Run the CCC two times.	Initiate the CCC cycle as you would initiate an external Electronic Simulator cycle. The instrument will identify the CCC as an external Electronic Simulator and display a Simulator Failure Code (i.e. rRGL) when the cycle is complete. Disregard the code, as this is expected behavior.
3. Update the CCC Usage Log	The log is located on page 3 of the Technical Bulletin entitled "Instructions for Restoring Analyzers That Produce *** for Hematocrit and Quality Check Code 23", which is shipped with the CCC. Updating the log allows the user to keep track of the number of pin conditioning cycles performed with the current ceramic strip in the CCC. If necessary, replace or rotate the ceramic strip so the CCC is ready for future use.
4. Return the analyzer to service.	

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ANALYZER FUNCTIONS

Introduction   The i-STAT 1 analyzer is a microprocessor-controlled electromechanical instrument designed to:

- identify the cartridge type.

- control the flow of fluids within the cartridges.

- mix sample and reagent (where applicable).

- apply electrical signals to certain types of sensors within the cartridges.

- control the temperature of the cartridge at 37°C (where applicable).

- measure electrical signals generated by the sensors (cartridge and test strip).

- measure the barometric pressure of the surrounding environment (where applicable).

- calculate concentrations of analytes using the generated electrical signals.

- display the results in numerical values and on bar graphs (where applicable).

- communicate the results to a printer and computer.

- sense and communicate operational errors.

- maintain an internal clock/calendar.

- store all test records, Electronic Simulator results and Quality Check Codes and messages.

Microprocessor System   The microprocessor control system manages all functions of the analyzer. It accesses three types of memory storage devices. A "FLASH" EEPROM module stores the software program in the analyzer. The RAM, which is backed up by an internal lithium battery, is used for temporary storage of sensor signals measured during operation and for storage of test records. Another EEPROM stores factory calibration information, the instrument serial number and cumulative count of uses. Neither of the EEPROMs relies on the lithium battery for maintaining information.

Sensor Interface   Electrical signals from the cartridge sensors are conducted from the contact pads on the cartridge, through the internal connector in the analyzer, to the sensor interface circuit board. Electrical signals from the test strip sensor are conducted from the contact bars to a sensor interface circuit board. These circuits amplify the signals from the sensors so that they can be further processed by the main electronic circuit board. Four signals are relayed to the main electronic circuit board from the cartridge sensor interface circuit board:

- A multiplexed potentiometric signal line

- A multiplexed amperometric signal line

- An AC fluid conductivity signal

- A digital identification code to identify the type of cartridge being inserted into the analyzer

Mechanical System

A single DC gearmotor drives mechanical system components:

- An electrical interconnecting system which brings the analyzer's electrical internal connector into contact with the contact pads on the cartridge

- A calibrant delivery system

- A sample delivery system

- A thermal control interconnectivity system which brings the analyzer's thermal controller into contact with heater elements on the back of cartridges. In addition, a latching mechanism locks the cartridge into place upon insertion.

Analog-to-Digital Conversion

An analog-to-digital converter converts all analog signals into digital form so that the microprocessor can perform mathematical calculations on the signals. An analog signal multiplexer makes it possible for the microprocessor to measure eight different types of analog signals:

- The potentiometric signals from the sensor interface circuit

- The amperometric signals from the cartridge and test strip sensor interface circuits

- A DC conductivity signal

- The battery voltage

- A thermistor signal representing the internal temperature of the analyzer

- A motor feedback signal used to control the speed of the mechanical motion

- Cartridge temperature signals used to control the cartridge temperature to 37°C

- A pressure transducer signal representing the barometric pressure of the environment

Analog Control Signals

The analyzer creates and applies two types of signals to the sensors: a digital-to-analog converter generates a voltage which is applied to amperometric sensors, and the AC conductivity circuit generates an AC excitation signal which is applied to the conductivity sensors. The digital-to-analog converter also provides voltages to the motor driver circuit.

Operator Interface

The microprocessor control system coordinates the reading of information input by the user, the writing of information onto the display, and the communication of results. The microprocessor control system, also, communicates with a clock/calendar circuit allowing the operator to set and read the time and date. The clock/calendar circuit is backed up by a lithium battery.

ELECTROCHEMICAL MEASUREMENTS

Method
Measurements are performed on undiluted specimens. Undiluted methods are also called direct methods, while methods requiring dilution of the sample are called indirect methods.

Indirect methods measure the total molar concentration of analyte per unit volume of plasma. Direct methods measure the total molar activity of analyte (apparent or free ion activity) per unit volume of plasma water. It is understood that the direct method result is the clinically significant result for electrolytes. When there is disagreement between the methods, such as when the patient has abnormal total protein or lipid levels, it is due to interference on the indirect method.

At normal levels of protein and lipids the systematic offset between methods is often corrected for in commercial direct measuring instruments so that the normal ranges for all instruments are in agreement. Sensor outputs have been set so that normal ranges are in agreement with indirect reference methods at normal levels of total protein and lipids.

Sensors
The general term "sensor" is used to refer to the three types of electrodes incorporated into the cartridges:

- Potentiometric
- Amperometric
- Conductometric

Sensors are thin film electrodes microfabricated onto silicon chips. Sensing functionality is imparted to each electrode by a number of chemically sensitive films coated over the active region of the electrodes.

Potentiometric Sensors
Potentiometry is the measurement of the difference in potential that exists between an indicator electrode and a reference electrode. Ion-selective electrodes (ISE) are examples of potentiometric sensors. The indicator electrode is designed to be sensitive to a particular ion in a solution. In cases where other ions are sensed by the system, selectivity coefficients can be used to correct for this interference. An enzyme can be added to an ISE to produce ions from analytes of interest that are not themselves ions.

The Nernst Equation
The Nernst equation relates the measured potential to the activity of the ion being measured.

$E = E° + RT/nF \ln a$

Where E is the potential, E° is a constant dependent on the electrode/sensor system, R is the gas constant, T is the absolute temperature, F is Faraday's constant, (n) is the valance (positive or negative charge) for the ion being measured, and (a) is the activity of that ion.

The Nernst equation can be rewritten as:

$E = E° + S \log a$

Where S replaces the constant term which defines the slope of the sensor. The slope is the change in millivolts per tenfold change in the activity of the analyte. For a positively-charged monovalent ion, the theoretical slope would be 59.1 mV at 25°C.

Activity Versus Concentration

Ion-selective electrodes measure activity rather than concentration. Activity (a) is related to concentration (c) through the activity coefficient (γ): $a = \gamma c$.

While ion activities, which reflect free rather than total ion concentrations, are the physiologically relevant quantity, activity values are converted to conventional concentration units so that values obtained by direct ISE measurements can be compared to values obtained from methods that measure total ion concentrations. The latter includes the indirect methods, which have activity coefficients close to unity or one, and flame photometric, atomic absorption and titration methods.

Amperometric Sensors

In amperometric measurements, a potential is applied to the measuring electrode while current generated by the resulting oxidation or reduction reactions in the test system is measured. The current generated is directly proportional to the concentration of the analyte. An enzyme can be added to a layer on or near an amperometric sensor to produce electroactive species from analytes of interest that cannot themselves be oxidized or reduced.

Conductometric Sensors

In a conductometric measurement, an alternating current is applied between two electrodes in contact with the test solution and the resulting voltage difference is measured. The conductivity of the solution is proportional to the magnitude of the voltage difference. In aqueous solutions, conductivity is dependent upon the concentration of electrolytes; an increase in the electrolyte concentration causes an increase in conductivity.

DETERMINATION OF TEST RESULTS

Determination of Analyte Concentration

Potentiometric and amperometric sensors are used for the determination of analyte concentration. For both sensors, the concentration of the analyte can be calculated using:

1) the known value of the analyte concentration in the calibrant solution,

2) the measured voltage (potentiometric) or current (amperometric) signal generated by the analyte in the calibrant, and

3) the measured signal generated by the analyte in the test solution.

For potentiometric sensors, the analyte activity in the sample is calculated from the Nernst equation according to:

$E_{sample} - E_{calibrant} = S \log (a_{sample}/a_{calibrant})$.

Complex solutions such as blood deviate slightly from Nernstian behavior due to interfering ions and matrix effects that result in junction potentials. By including selectivity coefficients in the Nernst equation (Nikolsky equation), these effects can be minimized. By characterizing the reference electrode in different solutions, effects of matrix on the reference junction potential can also be minimized.

It is known that direct methods read up to 7% higher than indirect methods in measuring the concentration of electrolytes. This is because there is an excluded volume occupied by plasma protein and lipids that is not considered in indirect measurements. Typically, however, the elevation of results is less than the full 7% because some of the analyte is bound to protein and other ions, and is not assayed by direct methods. For each analyte this discrepancy is characterized, and the result of the direct measurement is adjusted so that normal ranges are in agreement with indirect reference methods at normal levels of total protein and lipids.

DETERMINATION OF CELL CONCENTRATION

Hematocrit

In whole blood, plasma conducts electricity while the cellular constituents, red and white blood cells and platelets, do not. For a sample of a given electrolyte concentration, as the number of cells per unit volume of plasma increases, the conductivity of the sample decreases. The total cell concentration in whole blood can, therefore, be determined from:

1) the known electrolyte concentration of the calibrant,

2) the measured electrolyte concentration of the sample,

3) the measured conductivity of the calibrant and

4) the measured conductivity of the sample.

These measured quantities are determined using a combination of potentiometric and conductometric sensors.

Direct measurement of hematocrit by the conductometric technique gives a result related to the non-conducting excluded volume fraction of the sample fluid. Red blood cell volume is the predominant component of the non-conducting volume, but proteins, lipids, and white blood cells also contribute. Elevated hematocrit readings are expected at abnormally elevated levels of these components. Decreased hematocrit readings are expected at abnormally low levels of protein, such as found in hemodiluted samples taken from patients on cardiopulmonary bypass.

Osmotic imbalance causes a discrepancy between direct (conductometric, spun) and indirect (Coulter) measurements because of variation in the mean cell volume.

CPB

Each time a cartridge containing a hematocrit sensor is used, the operator has the option of selecting, in addition to the sample type, the CPB compensation algorithm for samples with abnormally low protein levels. The CPB option is specifically intended for use when samples are collected from patients on cardiopulmonary bypass. However, the facility may validate its use for other patient populations known to have protein levels significantly lower than the normal adult population.

The CPB algorithm infers the total protein level by assuming the pump priming solution dilutes the hematocrit and total protein equally. Modeling the pre-pump hematocrit as 43 %PCV and the pre-pump total protein as 7.0 g/dL, the following graph indicates the inferred total protein and resultant correction.

CPB Hematocrit Analysis

TP, pre CPB = 7.0   Hct, pre CPB = 42
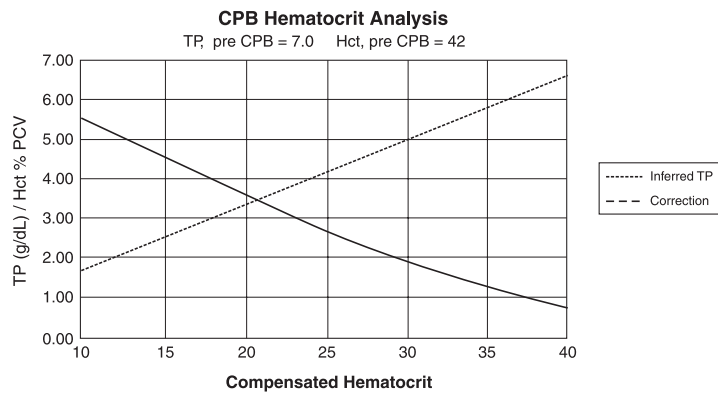
For example:

- uncompensated Hct = 21 %PCV

- 21 %PCV = 0.50 of 42 %

- inferred total protein = 7.0g/dL x 0.50 = 3.5 g/dL

- 21 %PCV + 3 g/dL = 24 %PCV (CPB)

Limitations of the CPB Algorithm

The CPB algorithm is based upon a series of inferences:

- The algorithm models initial pre-pump values for total protein and hematocrit. Although actual initial values may be different than those used in the algorithm, typical deviations rarely affect the accuracy of the correction by more than 0.5 %PCV. More often than not, the actual values are consistent with a "pre-dilution" of the modeled values.

- The algorithm assumes that the pump priming solution has no added albumin or other colloid. The algorithm will tend to overcorrect if solutions with added colloids are utilized, though the size of the over-correction will seldom be more than 1 %PCV.

- Other therapies which affect the ratio of total colloids to hemaotcrit (administration of colloids, packed red blood cells, etc.) will affect the interference.

When to discontinue use of the CPB algorithm will depend on when the patient's total protein level reaches the pre-pump level.

It is recommended that each practice verify the hematocrit determination for cardiopulmonary bypass procedures so that the impact of these limitations upon a particular practice's protocol is understood.

DETERMINATION OF COAGULATION ENDPOINTS

ACT and PT/INR In coagulation tests, the result that is reported is the time required for the process of coagulation to occur. To determine this time, there must be a detectable change in a sample parameter correlated to progression of the process. In traditional coagulation tests, endpoint detection typically relies on monitoring increases in either blood viscosity or plasma turbidity that occurs as thrombin converts fibrinogen to clotable fibrin. In an electrogenic test an electroactive marker that can be detected at either an amperometric or potentiometric sensor is used to indicate the endpoint. The marker is generated when a substrate that has been added to the test sample is acted upon by thrombin. As the coagulation reaction proceeds, the marker concentration increases, increasing the signal at the sensing electrode. The time required for generation of the marker correlates to the time required for conversion of fibrinogen. The coagulation endpoint can, therefore, be determined by monitoring the marker concentration. Unlike traditional coagulation tests, electrogenic tests will not be prolonged in samples with abnormally low (less than 100 mg/dL) fibrinogen levels.

QUALITY CONTROL AND THE i-STAT SYSTEM

Overview Quality control, as a component of an overall quality assurance program, consists of tests and procedures for monitoring and evaluating the analytical performance of a measurement system to assure the reliability of patient test results.

As new technologies evolve, quality control regimens must match the requirements of the particular analytical system. Abbott Point of Care recognizes the importance of effective quality control for its analytical medical devices, and has developed a program that is tailored to the unique characteristics of the i-STAT System.

The i STAT System performs blood analysis when a unit-use cartridge filled with a patient's sample is inserted into a handheld analyzer.

The measurement methodologies are electrochemical, using microfabricated sensors housed in each cartridge to measure analyte concentrations directly in a single whole blood sample (i.e., neither dilution nor reagent mixing steps are required).

i-STAT's microfabrication production processes are inherently capable of creating sensors with highly reproducible characteristics. For the measurement of blood gases, electrolytes and chemistries, this means that the i-STAT System requires only a one-point calibration, using a calibrant solution packaged in the cartridge, to meet the demanding requirements for clinical accuracy. As described in the Quality Control section of the i-STAT System Manual, the calibrant solution is also used to verify the integrity of the sensors as a key component of the quality system.

Two characteristics of the i-STAT System, which distinguish it from traditional laboratory equipment, have significant impact upon the design of the quality control regimen: its intended user and the unit-use cartridge technology.

As the system is intended to be used by individuals not trained in laboratory science, the onus is upon the system's design to ensure that the quality of results is not dependent upon either user technique, skilled maintenance and calibration procedures, or the accompanying quality control regimens which ensure these procedures have been properly performed.

The use of unit-use cartridges frees the i-STAT System from these skilled maintenance and calibration procedures. It also allows for the design of a quality control system which automatically monitors those aspects of the measurement process which are the most likely to impact quality, including the characteristics of the individual sensors and the operator's actions.

i-STAT's quality control regimen has four aspects, resting on the foundation of a system design which reduces the opportunity for the type of error which traditional quality control regimens are designed to detect:

1) A series of automated, on-line quality measurements that monitor the sensors, fluidics and instrumentation each time a test is performed.

2) A series of automated, on-line procedural checks monitors the user each time a test is performed.

3) Liquid materials are used to verify the performance of a batch of cartridges when they are first received or when storage conditions are in question.

4) Traditional quality control measurements verify the instrumentation using an independent device, which simulates the characteristics of the electrochemical sensors in a way which stresses the performance characteristics of the instrumentation.

Similarities to Traditional Laboratory Quality Control Regimen

Although the more significant aspects of i-STAT's quality control regimen are the quality checks automatically performed with each unit-use cartridge, many principles of the quality control regimen are similar to traditional regimens.

Laboratory quality control methods are statistical. They assess the quality of the measurement process by intermittently inserting pseudosamples (controls) into the stream of samples being tested.

The approach implicitly assumes that the elements of the measuring system persist from run to run so that the repeatability and accuracy of the measurement of patient samples can be predicted by the repeatability and accuracy of pseudosamples.

The i STAT system uses an analogous approach to monitor the part of the testing process which persists from run to run – the handheld analyzer.

An Electronic Simulator, which mimics the electrical characteristics of the signals produced by the sensors, is inserted into the handheld analyzer on a daily basis. The Simulator produces signals consistent with both very low and very high concentrations of each of the analytes. The handheld analyzer causes the Simulator to change the signals via a control signal.

The software in the handheld analyzer measures these signals as it would measure signals from a cartridge. The software checks the measurements against predetermined thresholds and indicates their acceptability to the user via a PASS/FAIL message.

All analyzers that pass the Electronic Simulator test are equivalent. Therefore, any representative number of analyzers that pass the simulator test may be used for compliance with regulatory and accreditation quality assurance procedures. These procedures include initial performance verification studies, calibration verification, proficiency testing, and method comparison studies.

An important aspect of the Simulator is that it mimics the sensitive nature of the sensor's signals to ensure that the adjacent input channels within the handheld analyzer maintain the required degree of electrical isolation from each other to prevent "crosstalk" (see US Patent #51246661 for details). This cannot be achieved by the traditional internal self-consistency checks characteristic of modern microprocessor-controlled instrumentation.

Comparison of this regimen to laboratory quality control procedures can seem confusing because it does not employ liquid control solutions. However, the principle is the same in that the traditional intermittent quality control measurements are applied to the persistent part of the system. In the case of the i-STAT System, only the instrumentation is persistent so only this portion is tested with an external challenge.

Further, use of an electronic quality control device has distinct quality advantages:

1) Non-laboratory-trained individuals do not need to interpret control results because the analyzer software, expecting certain simulator signals, automates the interpretation. In comparison, many quality control regimens using liquid controls at the point of care are ineffective because an out-of-control result is easy to ignore.

2) Injecting signals into the handheld analyzer allows very tight control limits to be set. Control limits using liquid controls at the point of care are generally very wide to allow for sensor-to-sensor variation.

The i-STAT Unit-Use Cartridge as an Element of Design Robustness for Point-of-Care Testing

The most important quality measure in the i-STAT System is that it is designed to reliably deliver quality results in the hands of individuals not trained in laboratory science. It addresses those aspects of the design in traditional laboratory-based equipment and other point-of-care devices which detract from robustness in the hands of these individuals.

1) In the interest of making batch processing efficient, laboratory devices make extensive use of components which are exposed to each test sample (sensors, tubing, etc.). These devices must be continuously recalibrated as successive samples interact with these elements. Quality control regimens are designed to detect incorrect or required calibrations.

   All elements which are exposed to the test sample are unit-use in the i-STAT System. Many of the out-of-control conditions which a laboratory quality control regimen is designed to catch simply do not exist.

   Furthermore, the use of unit-use devices is directly related to the design of i STAT's quality approach. Each test begins with fresh sensors and a fresh calibrant fluid, if applicable. The response of the sensors' signals to the fresh calibrant fluid, if applicable, is well characterized from a large database of tests run in i STAT's manufacturing facility. If the sensor signal is uncharacteristic due to mismanufacture, mishandling or misstorage, the handheld analyzer software will suppress the result (displays "***").

2) Many point-of-care devices require the non laboratory-trained user to interact directly with the sensing elements (paper strip technologies for example). Many Point-of-Care Coordinators rely heavily on the daily quality control regimen not only as a means for monitoring system performance, but more significantly, as a means for monitoring user proficiency.

The analyzer controls all fluid motions in the i-STAT System. The calibrant, if applicable, and sample are brought to the sensors under instrument control so that the user does not directly impact on the quality of the analytical process and therefore cannot impinge on the quality of the results.

Further, the analyzer uses a fluid sensor to electronically verify the proper flow of fluids within the cartridge on every run. This can easily be demonstrated by attempting to fool the system by:

- putting in too much sample
- putting in too little sample
- rerunning the same cartridge
- introducing an air segment into the fluid segment, etc. The analyzer will flag these conditions and not deliver a result.

3) The design of some unit-use point-of-care devices can allow an entire batch of unit-use devices to be affected by a single event, for example, by leaving a tube of paper strips open and exposed to a high humidity environment.

With the i-STAT System, each unitized device is sealed in a separate foil pouch and has its own individual history. The only external factor, which can create a shared history among cartridges, is temperature. This is controlled by appropriately monitoring the storage environment.

The Foundation of i-STAT's Quality Control Regimen – On-Line Tests

The fundamental backbone of i-STAT's quality regimen is the series of automatic checks performed each time a cartridge is run.

The tables below list the key elements and operations of the i-STAT System that are verified **each time** a cartridge is used.

For completeness, those operations which are qualified by the Electronic Simulator are also listed.

Unit-Use Cartridge

Verification	When Verified
Microfabricated Electrochemical Sensor Elements	
• verify sensors are present	Every cartridge use
• verify sensor characteristics are consistent with expectations of a properly manufactured and maintained device (by testing calibration fluid), if applicable	Every cartridge use
Calibration Fluid (if applicable)	
• verify fluid is present	Every cartridge use
• verify fluid is delivered free of bubbles	Every cartridge use
• verify fluid has proper concentration	Every cartridge use
Fluidic System	
• verify sample holding chamber is sealed	Every cartridge use
• verify fluid flowpaths are intact (no part of the analyzer comes into direct contact with fluid)	Every cartridge use
• verify waste chamber is not occluded	Every cartridge use
Elements that interact with the handheld analyzer	
• verify electrical contact pads (that allow access to sensor signals) are unoccluded	Every cartridge use
• verify internal element of cartridge that allows the handheld analyzer to control the release of calibration fluid, if applicable, over the sensors is functioning properly.	Every cartridge use
• verify internal element of cartridge that allows the analyzer to control the replacement of calibration fluid, if applicable, with sample is functioning properly	Every cartridge use

Handheld Analyzer

Verification	When Verified
Motorized Mechanical System	
• verify electrical contact is made with sensors on cartridge	Every cartridge use
• verify ability to properly move calibration fluid, if applicable	Every cartridge use
• verify ability to properly move sample	Every cartridge use
Electrical Measurement System	
• verify voltage measuring system for potentiometric sensors	Electronic Simulator
• verify current measuring system for amperometric sensors	Electronic Simulator
• verify resistance measuring system for conductometric sensors	Electronic Simulator
Other	
• verify internal self-consistency of electronic systems	Every cartridge use
• verify fluid flow using the conductivity sensor	Every cartridge use
• verify function of transducers used for measuring barometric pressure	Every cartridge use
• verify function of the thermistors used to control chip temperature	Electronic Simulator

Operator Sample Handling/Cartridge

Verification	When Verified
Verify the cartridge inserted has not been previously used	Every cartridge use
Verify the calibrant pack, if applicable, has not prematurely ruptured	Every cartridge use
Verify the electronic contact pads are dry and uncontaminated	Every cartridge use
Verify the proper amount of sample was placed into the sample chamber	Every cartridge use
Verify the sample was properly positioned within the sample chamber	Every cartridge use
Verify the sample is free of included bubbles	Every cartridge use
Verify the sample is not clotted	Every cartridge use
Verify the sample chamber is properly sealed with the closure	Every cartridge use

Validating the Performance of the i-STAT System

Until recently, regulations and laboratory accreditation standards specified the use of traditional quality control regimens, including the daily use of liquid "control" materials.

As new technologies such as the i-STAT System have become available, the community has recognized the limitations of relying upon traditional regimens, prompting various regulatory and accreditation organizations to modify their standards accordingly.

Many of the newly drafted regulations and accreditation standards recognize the danger of denoting specific methods of achieving an effective quality control regimen. Additionally, specific methods cannot anticipate future technological changes, so many of the regulatory and accreditation organizations are changing their standards to place the responsibility of establishing and validating the quality system a laboratory employs on the laboratory director.

Quality control regimens should be established using information from the manufacturer and scientific literature.

It is important to validate the performance of the i-STAT System and the recommended quality control regimen to develop personal confidence in our approach to the challenges of putting a diagnostic device in the hands of individuals untrained in laboratory science.

Some of the regulatory and accreditation organizations recommend the daily use of liquid "control" materials for the first month of use, slowly stepping back the frequency as a database of performance information increases confidence levels. The number of lots of materials examined should also be considered when determining a validation protocol.

QUALITY CONTROL AND THE i-STAT COAGULATION TESTS

Operating Principles of the Coagulation Cartridge–Overview

The i-STAT coagulation cartridges measure the time required for complete activation of the coagulation cascade once initiated by the activator. Coagulation instruments determine this time by sensing a characteristic change in a measured property of the sample. In the i-STAT System the measured property is the concentration of an electroactive marker. The time to clot is indicated by a relative increase in the concentration as measured by an amperometric sensor.

i-STAT dries the activator and a precursor of the electrochemical marker (a substrate to the thrombin enzyme produced by the coagulation cascade) onto the wall of the reaction chamber during the manufacturing process. At the beginning of the test the system agitates the blood back and forth across the chamber wall to mix these reagents into the blood sample.

Quality System for Coagulation Cartridge

The critical performance feature of the coagulation cartridge centers on the repeatability of the reagent mixing process. The accuracy to which the reagent is mixed into the blood sample directly impacts the accuracy of the result.

The system quantitatively confirms the accuracy of the mixing step by monitoring the key parameters of mix uniformity, magnitude and timing. These quality tests are performed on each coagulation cartridge.

i-STAT's microfabrication production processes are inherently capable of creating sensors with highly reproducible characteristics. For the measurement of blood gases, electrolytes and chemistries, this means that the i-STAT System requires only a one-point calibration, using a calibrant solution packaged in the cartridge, to meet the demanding requirements for clinical accuracy. As described in the Quality Control section of the i-STAT System Manual, the calibrant solution is also used to verify the integrity of the sensors as a key component of the quality system.

For the measurement of ACT and PT, the required accuracy for the amperometric sensor to detect the relative increase in concentration of the electroactive marker is more modest. A calibrant solution is required neither for a one-point calibration nor to verify the wetup characteristics of the sensor. Instead, the magnitude and rate of change of current is assessed quantitatively throughout the test in order to verify the quality of the mix, and the integrity of both the sensor and the reagent coating.

Regulatory Aspects of the Quality System for Coagulation

Alternatives to traditional quality systems have been developed that are suitable for ensuring the performance of unit-use in-vitro diagnostic systems. These alternative systems rely upon a variety of internal self-tests and electronic/optical checks. As unit-use devices have become more widespread in clinical practice, regulations and guidance documents have adapted to recognize the effectiveness of these alternative quality systems, albeit with some variation. For example, some state regulations require that the alternative quality system include an on-board "wet" control. The i-STAT Quality System for the coagulation test is able to address this requirement even though the cartridge does not contain an on-board wet calibration fluid. The quantitative confirmation that the activator and the marker are accurately mixed into the blood sample is a "wet" test that acts as a control of the most critical aspect of the coagulation test.

Electronic Quality Control

i-STAT's electronic simulator (both the internal and external versions) check the amperometric and conductivity circuitry used in the coagulation tests at multiple levels. The instrument checks the accuracy of the measurement of elapsed time each time a test is run by comparing the clock rates from two independent clocking circuits. The instrument also runs a battery of general instrument checks during each test.

PROGRAMMING THE NETWORK DOWNLOADERS

This section includes procedures to configure the network Downloaders to transmit data between the i-STAT 1 Analyzers and a data manager as well as from other peripheral devices to a computer running CDS.

Preparation

1. Determine for each Downloader: IP Address, Gateway Address, and Subnet Mask.

2. Determine the IP Address of the data manager and service port for i-STAT 1 Analyzer transmissions (default 6004).

Configure a Terminal Session

1. Run a terminal emulation program, such as HyperTerminal, and choose the following port settings:

> Bits per second: **9600**
> Data bits: **8**
> Parity: **None**
> Stop Bits: **1**
> Flow Control: **None**

Connect to and Program the Downloader

1. Connect one end of a Null-Modem Cable to the DB9 Port on the Downloader and connect the other end to the COM port selected in the Hyper Terminal session above to the computer with Hyper Terminal as shown below. **Do not apply power to the Downloader at this time**.

> ① Power In
>
> ② DB9
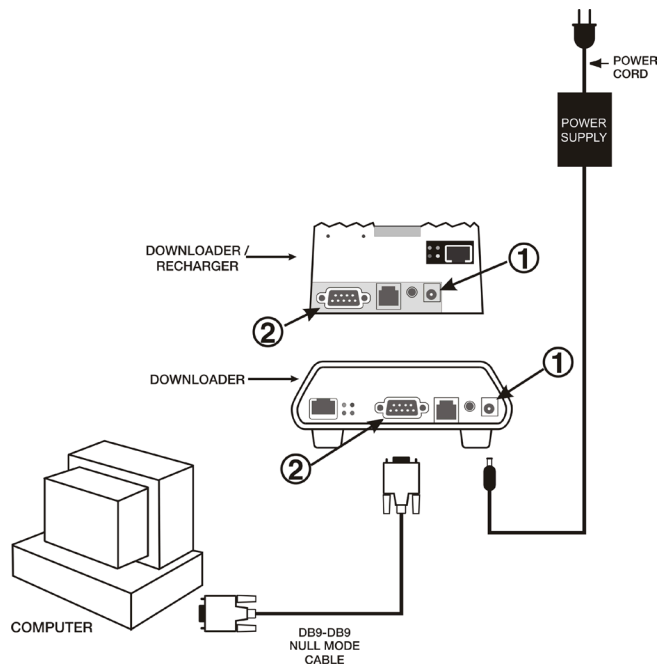
2. While holding down the **x** key on the PC keyboard, apply power to the Downloader. When the following screen is displayed release the **x** key:

```
*** Lantronix Cobox Universal Device Server ***
Serial Number 265-101  Software Version V03.9 (000211)
Press Enter to go into Setup Mode
```

3. Press the Enter key immediately to enter the Setup Mode:

```
Hardware: Ethernet Autodetect
IP addr - 0.0.0.0/DHCP , no gateway set

***************** Channel 1 *****************
Baudrate 19200, I/F Mode 4C, Flow 00
Port 10001
Remote IP Adr: --- none ---, Port 00000
Connect Mode: C1  Disconn Mode: 00  Disconn Time: 00:30
Flush   Mode: 44

***************** Channel 2 *****************
Baudrate 38400, I/F Mode 4C, Flow 00
Port 10002
Remote IP Adr: --- none ---, Port 06004
Connect Mode: C1  Disconn Mode: 00  Disconn Time: 00:30
Flush   Mode: 44

Change Setup  : 0 Server configuration
                1 Channel 1 configuration
                2 Channel 2 configuration
                7 Factory defaults
                8 Exit without save
                9 Save and exit          Your choice ? _
```

Configure Server Parameters

Each network Downloader requires a static IP Address, a Gateway Address, and, if required, a Subnet Mask.

Note: **Failure to assign a <u>static</u> IP address to the downloader could result in an i-STAT 1 Analyzer being programmed with an inappropriate customization profile.**

The following describes how to configure the network Downloader's server parameters.

1. Determine the following site specific information for this Downloader:
   - IP Address (Example: 10.10.12.142 used below)
   - Gateway Address (Example: 10.10.12.1 used below)
   - Netmask (Example: 8 for 255.255.255.0 used below)

2. At the **Your choice?** prompt, Select **0** for Server Configuration and enter the information required for this Downloader.

3. At each of the prompts enter the bold-faced value.

   Note: If the information to be entered is the same as the default value, press the Enter key.

   - IP Address: (000)**10**.(000) **10**.(000)**12**.(000)**142**
   - Set Gateway IP Address: (N) **Y**
   - Gateway IP addr: (000)**10**.(000)**10**.(000)**12**.(000) **1**
   - Netmask: Number of Bits for Host Part (00) **8**

   Note: The Netmask is configured as the number of host bits required based on the subnet being used.

   - Change telnet config password: (N) **N**

Default Netmasks for Standard IP Networks

Subnet Mask	Host Bits	Network Type
255.0.0.0	24	Class A
255.255.0.0	16	Class B
255.255.255.0	8	Class C

Netmasks for Other Networks

Subnet Mask	Host Bits	Subnet Mask	Host Bits
255.255.255.252	2	255.255.192.0	14
255.255.255.248	3	255.255.128.0	15
255.255.255.240	4	255.255.0.0	16
255.255.255.224	5	255.254.0.0	17
255.255.255.192	6	255.252.0.0	18
255.255.255.128	7	255.248.0.0	19
255.255.255.0	8	255.240.0.0	20
255.255.254.0	9	255.224.0.0	21
255.255.252.0	10	255.192.0.0	22
255.255.248.0	11	255.128.0.0	23
255.255.240.0	12	255.0.0.0	24
255.255.224.0	13		

Configure for i-STAT 1 Data Transfer via IR Port

Channel 2 provides network access for the i-STAT 1 Analyzer data transmissions to a data manager. This section describes how to set up parameters for Channel 2.

1. Determine the following information:

    - The IP Address of the data manager. (Example: 10.10.12.184)

    - The service port number set to receive transmissions from the i-STAT 1 Analyzer (default 6004).

2. At the **Your choice ?** prompt, Select **2** (Channel 2 Configuration).

3. At each of the prompts enter the following bold-faced value:

    Note: If the information to be entered is the same as the default value, press the Enter key.

    - Baudrate (38400) ? **38400** (*must be set to 38400*)

    - I/F Mode (4C) ? (*press <Enter> key*)

    - Flow (00) ? (*press <Enter> key*)

    - Port No (10002) ? (*press <Enter> key*)

    - ConnectMode (C1) ? **C1** (*must be set to C1*)

    - Auto increment source port (N) ? **N** (*press <Enter> key*)

    - Remote IP Address : (000)**10**.(000)**10**.(000)**12**.(000) **184**

        Note: Set Remote IP Address to the IP Address of the computer where the data manager resides.

    - Remote Port (06004) ? **6004**

        Note: Remote Port refers to i-STAT 1 service port defined in the data manager.

    - DisConnMode (00) ? (*press <Enter> key*)

    - FlushMode   (44) ? **44** (*must be set to "44"*)

    - DisConnTime (00:30) ? **00:30** (*Disconnect time must be 30 seconds)*

    - SendChar 1 (00) ? (*press <Enter> key*)

    - SendChar 2 (00) ? (*press <Enter> key*)

Verify and Save Settings

1. When the Summary screen appears, verify that the information you entered is correct. If it is not, fix the appropriate settings and continue.

2. Save the settings by selecting **9** (Save and Exit) at the **Your choice ?** prompt.

3. Remove power and connect the Downloader in its intended location.

Troubleshooting

If a wrong number is entered, which cannot be corrected, press the **Enter** key until the session is completed and start from the beginning again.

Configure for i-STAT 1 Serial Downloader Connection

Channel 1 provides network access for the i-STAT 1 Analyzer data transmissions to a data manager. This section describes how to set up parameters for Channel 1.

1. Determine the following information:

   - The IP Address of the data manager. (Example: 10.10.12.184)
   - The service port number set to receive transmissions from the i-STAT 1 Analyzer (default 6004).

2. At the **Your choice ?** prompt, Select **1** (Channel 1 Configuration).

3. At each of the prompts enter the following bold-faced value:

   Note: If the information to be entered is the same as the default value, press the Enter key.
   - Baudrate (38400) ? **38400** (*must be set to 38400*)
   - I/F Mode (4C) ? (*press <Enter> key*)
   - Flow (00) ? (*press <Enter> key*)
   - Port No (10001) ? (*press <Enter> key*)
   - ConnectMode (C1) ? **C1** (*must be set to C1*)
   - Auto increment source port (N) ? **N** (*press <Enter> key*)
   - Remote IP Address : (000)**10**.(000)**10**.(000)**12**.(000) **184**
     Note: Set Remote IP Address to the IP Address of the computer where the data manager resides.
   - Remote Port (06004) ? **6004**
     Note: Remote Port refers to i-STAT 1 service port defined in the data manager.
   - DisConnMode (00) ? (*press <Enter> key*)
   - FlushMode (44) ? **44** (*must be set to "44"*)
   - DisConnTime (00:30) ? **00:30** (*Disconnect time must be 30 seconds)*
   - SendChar 1 (00) ? (*press <Enter> key*)
   - SendChar 2 (00) ? (*press <Enter> key*)

WIRING THE DOWNLOADERS

Overview   This section includes diagrams to make a connection between the Downloaders and the Data Manager and to connect a printer to the Downloaders.

Caution   Only i-STAT provided printers may be connected to the Downloader printer port.

An ethernet cable and serial (DB9) cable may <u>NOT</u> be connected to the Downloader at the same time.

Connecting the Network Downloader

Option 1: The following diagram shows how to connect the portable printer to the network Downloader for communication. Parts required are:

- Printer Interface Cable
- Printer Power Adapter
- ① Power In
- ② Power Out
- ③ RJ12 (printer interface)
- ④ DB9
- ⑤ RJ45 (network)
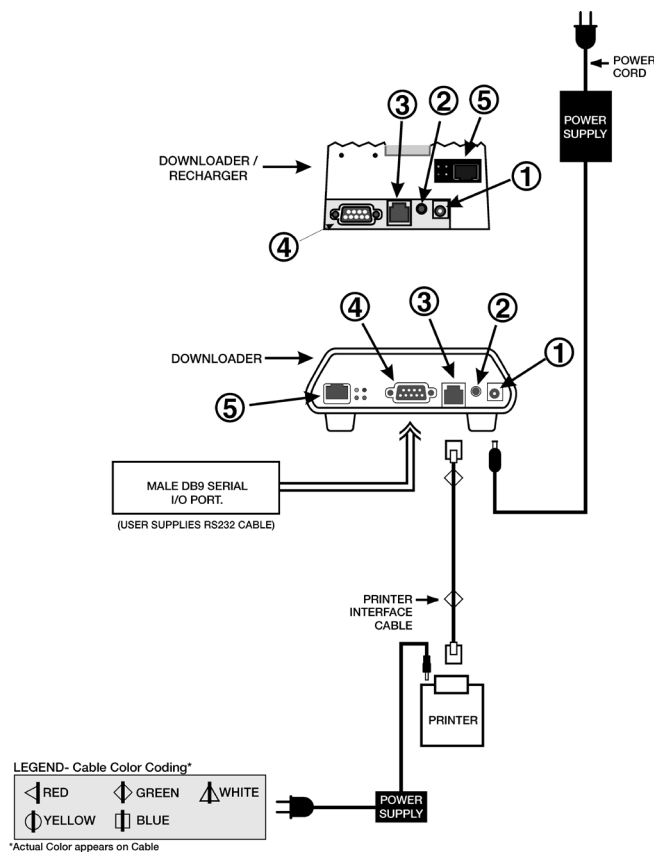
Option 2: The following diagram shows how to connect the portable printer to the network Downloader for power and communication. Parts required are:

- Printer Interface Cable
- Printer AC Adapter or Printer Power Cable
① Power In
② Power Out
③ RJ12 (printer interface)
④ DB9
⑤ RJ45 (network)

LEGEND- Cable Color Coding*

◁ RED   ◇ GREEN   △ WHITE

◐ YELLOW   ▯ BLUE
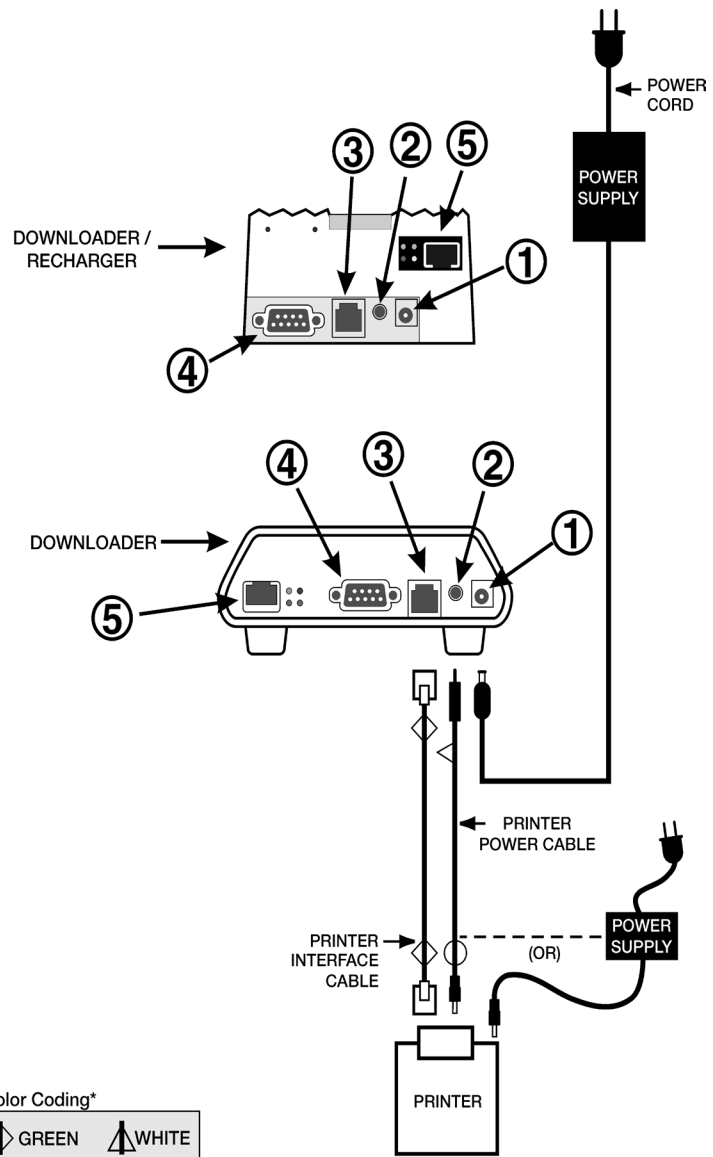
*Actual Color appears on Cable

Connecting the Serial Port Downloader

Option 1: The following option is for downloading/uploading only and can be used when there is no power outlet available for the Downloader or Downloader/Recharger.

In this particular configuration, both recharging LED lights will be lit. The primary recharging LED will blink red and the alternate will be steady green. This is typical behavior, and does not indicate that any charging is taking place. In fact, batteries cannot be charged in the Downloader/Recharger in this configuration.

The following diagram shows how to connect a serial downloader locally to the Data Manager. Parts required are:

- PC/Downloader Adapter
- DB9-DB9 Null Modem Cable
① Power In
② Power Out
③ RJ12 (printer interface)
④ DB9

Option 2: The following diagram shows how to connect a serial downloader to the Data Manager, and to connect the portable printer to the Downloader for communication. Parts required are:

- DB9-DB9 Null Modem Cable
- Printer Interface Cable
- Printer AC Adapter

① Power In

② Power Out

③ RJ12 (printer interface)

④ DB9
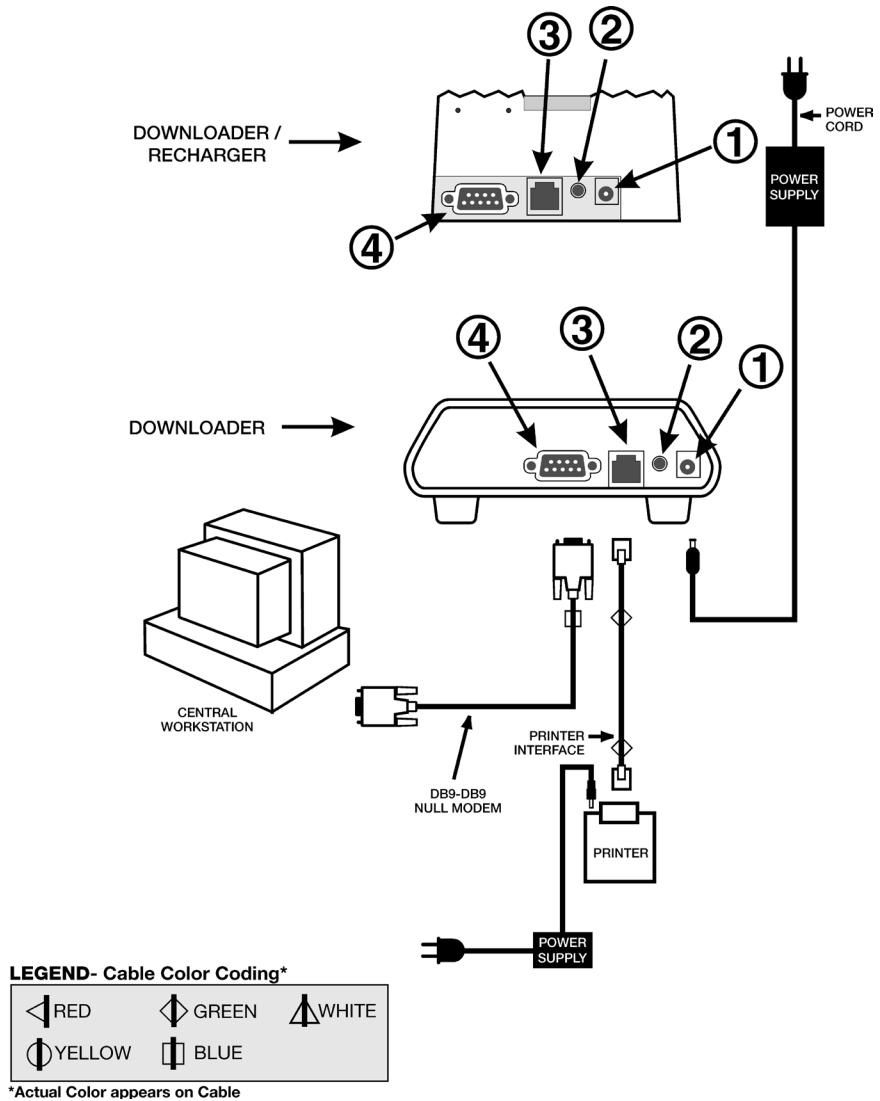
Option 3: The following diagram shows how to connect a serial downloader to the Data Manager, and to connect the portable printer to the Downloader for power and communication.   The printer can also be powered by its own AC adpater. Parts required are:

- DB9-DB9 Null Modem Cable
- Printer Interface Cable
- Printer Power Cable or Printer AC Adapter

① Power In

② Power Out

③ RJ12 (printer interface)

④ DB9

ABBOTT POINT OF CARE INC. LICENSE AGREEMENT AND WARRANTY FOR CENTRAL DATA STATION PROGRAM

EULA

For new users of CDS software the license and warranty information in the End User License Agreement (EULA) will be in effect.

License

The i-STAT Central Data Station software is licensed to the authorized user by Abbott Point of Care Inc. Portions of the software are licensed to you by Abbott Point of Care Inc. under sublicense from other original software providers. By accepting and using this software, the user/licensee agrees to the following:

- The user/licensee will not make copies of the software programs or any of the program software files generated by the programs, the manual or other documentation except for archive copies made as part of user/licensee's regular back-up procedures.

- The user/licensee will protect the programs from unauthorized use, illegal reproduction (including reproducing any of the software files generated by the programs) or illicit distribution.

- The user/licensee will not change or reverse engineer the programs or any of their software files by debugging, decompiling, disassembling, reprogramming, rewriting the programs' macros, revising the programs' forms or any other means.

If the user/licensee makes any use, transfer or disclosure of the programs in violation of any of the foregoing, the sub-license will, at the option of Abbott Point of Care Inc., immediately terminate without demand or notice and the user/licensee will immediately give to Abbott Point of Care Inc. the programs, the manuals and all copies thereof in the user/licensee's possession.

Warranty

Abbott Point of Care Inc. warrants the licensed software and accompanying physical documentation to be free of defects for a period of thirty days from the date of installation. If notified of defects within the warranty period, Abbott Point of Care Inc. will replace the defective software or documentation as soon as practical for the nature of the defect. The remedy for breach of this warranty is limited to replacement and shall not encompass any other damages including but not limited to loss of profit, and special, incidental, consequential or other similar claims. Abbott Point of Care Inc. specifically disclaims all other warranties, expressed or implied, including but not limited to implied warranties of merchantability and fitness for a particular purpose, with respect to the software, accompanying documentation and the license granted herein.

INSTALLATION OF THE CENTRAL DATA STATION

Hardware

The PC on which the CDS software resides must meet specifications provided by Abbott Point of Care Inc. and should be installed following the PC manufacturer's directions. Install the printer if applicable.

Software Installation: License Key

A license key is required to install the Central Data Station software. The license key ensures that the end user agrees to the License Agreement displayed during installation. To obtain the license key, follow the instructions present on the screen.

Caution

The use of other software that was not provided as part of the system on the same PC with the Central Data Station software may compromise the system, including permanent loss of patient records.

Site Specific Customization of the CDS

During installation, the CDS must be customized to properly communicate with i-STAT 1 Downloaders and Downloader/Rechargers, i-STAT IR Links and Philips Medical Systems Blood Analysis Modules throughout the hospital. The procedure to customize the CDS is described under the Customization section below.

The date displayed with results can be changed to any Short Date format and separator listed in the computer's Control Panel under Regional Options (or something similar, depending on the version of Microsoft Windows in use). If an unsupported format or separator is detected, the user will be notified and given the opportunity to change to a supported format/separator combination.

Connectivity

Basic information needed to connect the Downloaders, Downloader/Rechargers, and the portable printer to the PC are in the Downloader Wiring and Programming section of this manual.

For assistance in programming the Downloader, Downloader/Recharger and IR Links, contact your i-STAT support representative.

Interface

Basic information on interfacing can be found in the "Interface" paragraph under "Customization of the Central Data Station" in this section of this manual and in section 8.

GENERAL PROCEDURES AND CONVENTIONS

Overview

The CDS software follows typical Microsoft® Windows® conventions and procedures. The illustrations below are used to point out the use of the menu bar, toolbars, tabs and buttons.

Selecting Menu Options

Clicking an item on the menu bar (1) will drop down the menu for that item. If any of the items in the drop down menu has a submenu, the submenu will open to the right of the ▶ symbol next to the item when the item is highlighted (2).
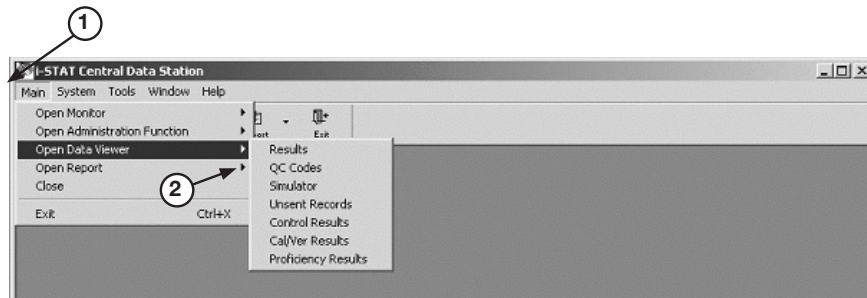
Clicking the ▼ beside a toolbar button (3) will drop down a submenu toolbar (4).
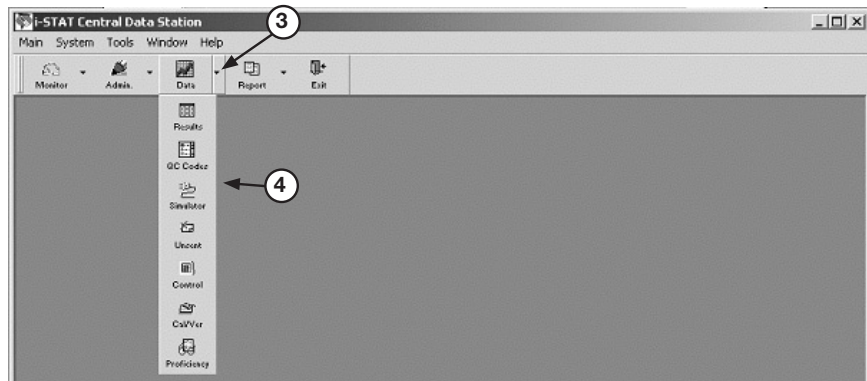
Clicking the desired menu option will open the item's window or will perform the item's function. The menu items and toolbar for the active window will be displayed (5).
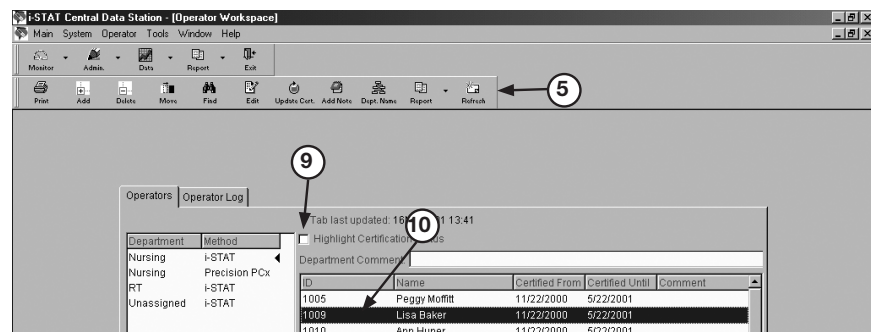
Selecting Functions in a Window

Tabs: A window may have several functional groupings that are contained in tabs (6) with multiple pages. Clicking the text on the tab will display the corresponding page.

Buttons: Use to activate a function within a window (7) or to confirm (OK) or cancel a function or to manipulate a window. All windows can have the following buttons in the upper right hand corner (8):
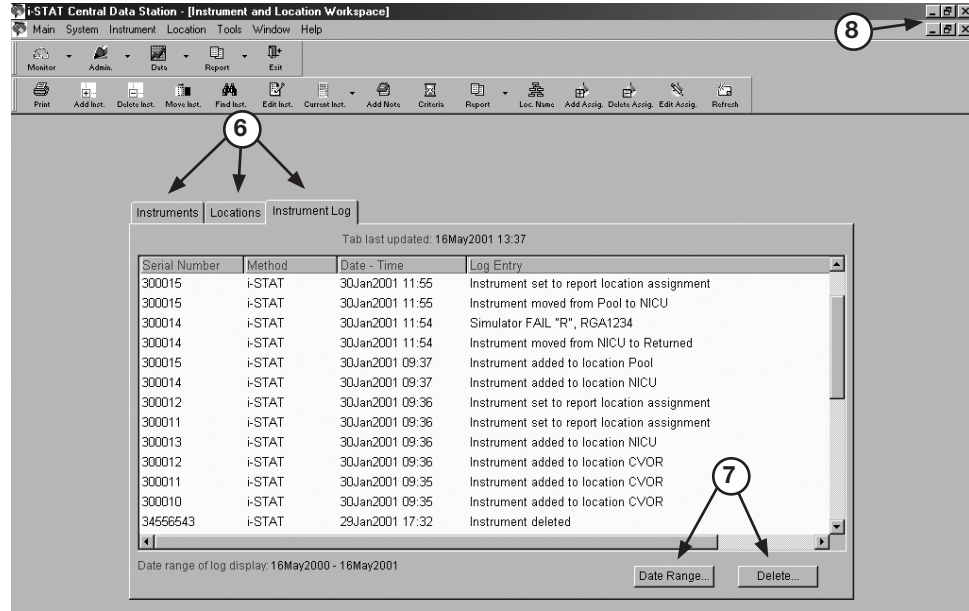
This button causes the window to be maximized.

This button causes the window to be minimized.

This button causes the window to be moveable and resizable.

This button causes the window to close.

If a window does not have a close button, it can be closed by selecting **Main** then **Close** on the menu bar.

Check boxes: Click the box to enable or disable a single option (9).

Radio buttons: Click the circle to select from a list of mutually exclusive options.

Highlight bar: Use to select the line or lines on which to apply a function (10).

Drop down list: Click the ▼ button to drop down a list or scroll downward in a window.

Refreshing/ Updating the Data in a Window

The **Refresh** toolbar button refreshes the data content in the active window with the most recent data available. The refresh function is also available under the Window option on the menu bar. Pressing **F5** will also refresh the data.

Sorting Data in a Window

In most cases, when data is presented in a table, clicking a column header will sort the display based on the data in that column. In the Data Viewers, repeating values, such as a patient ID, will be sorted in descending Date/Time order. Clicking the header again will reverse the order of the sort. To return the data to chronological order, click the Date-Time column header.

Selecting Multiple Lines

In many functions, multiple lines can be selected for the desired action. To select consecutive multiple lines, click the first line and, while holding down the **Shift** key, click the last line. To select multiple lines that are not consecutive, click the desired lines while holding down the **Ctrl** key.

Opening Multiple Windows

Multiple windows can be open at the same time. The **Windows** item on the menu bar can be used to select the desired window from the list of open windows and bring it to the forefront. Close windows by clicking the **Close** button at the top right of the window or by selecting **Close** from the **Main** menu.

Column Ordering

Columns in the Data Viewers can be placed in any order. Use the mouse to grab a column header and drag the column to the desired position.

Column Widths

To adjust a column's width in Data Viewers, place the mouse pointer on the edge of the column header. When the mouse pointer turns into two arrows, hold the left mouse key and drag column to the desired width.

Toolbars

Helpful Hint!

Select **Tools** ⇨ **Customize Toolbars...** to select options for the way toolbars appear. Checking **Large Buttons** displays descriptive text under toolbar buttons. This may be helpful while learning the application. Checking **Show Tooltips** displays a description of a button when the mouse pointer is placed over a toolbar button.

Art: 714384-00F

CUSTOMIZATION OF THE CENTRAL DATA STATION

Overview   The Customization options are:

Site Information	Institution name and technical support phone number
Serial Ports	Enables/Disables serial communications and allows individual ports to be selected and configured
Network	Enables/Disables network communications and allows specification of TCP port numbers
Interface	Enables/Disables external interfacing and allows protocol to be selected
Options	Allows various general system behaviors to be specified
Security	Enables/Disables the CDS Security features which allow for the creation of security profiles providing different levels of access to various areas and functions of the CDS application.

To access the Customization screen, close the CDS application, access the Run dialog box by clicking **Start** ⇨ **Run...**. Type **wcds32 config** at the **Open:** prompt, then click **OK**.

If **Run...** is not on the **Start** menu, double click the **Command Prompt** shortcut. At the **C:\>** prompt in the window that opens, type **c:\istat32\bin\wcds32.exe config** and press **Enter**.

When the Customization screen appears, click a tab to display the desired tab page. The information in each field can be specified. When all tabs are customized as desired, click the **Accept** button to save the information. Click the **Reset** button to disregard changes and restore the previous information. Click the **Cancel** button to ignore any changes and retain the current settings. When customization is complete, the CDS application will open automatically.

Site Information   A site name and address of up to 60 characters can be entered into this field.

The appropriate Technical Support Phone Number for the country will be listed or can be entered.
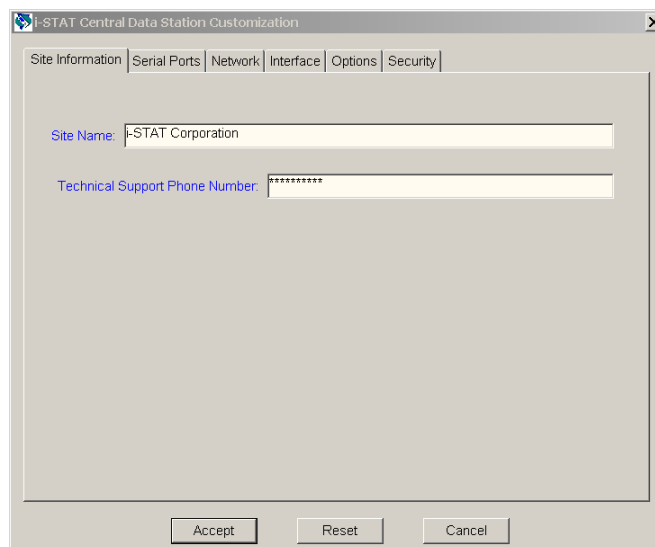
Serial Ports

The Central Data Station program resides on a PC with multiple serial ports (DB9). Available ports will automatically be listed under **Available Ports** on the Serial Ports tab page. The following components can be connected to the Central Data Station via serial ports:

❑ **i-STAT Series 200 Analyzer:** IR Link transmits data to and from the i-STAT Portable Clinical Analyzer.

❑ **i-STAT Series 300 Analyzer:** Downloader or Downloader/Recharger transmits data to and from the i-STAT 1 Analyzer.

❑ **Philips Module:** a local connection to the CDS is needed to transmit software updates and customization profiles to the Blood Analysis Module.

❑ **Philips CDS:** The CDS server transmits patient data from the Blood Analysis Module to the Data Manager.

Click the **Enable serial communications** box to check it and enable serial communications.

Click the desired port(s) under **Available Ports** and click the **<<<<Add** button. The port(s) will now be listed under **Configured Ports.**
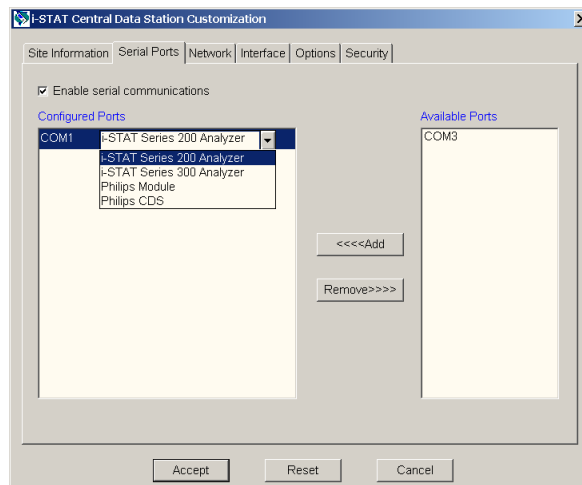
Click the port and select an instrument for that port.
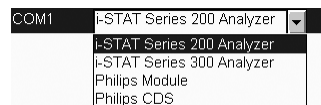
Serial ports on the PC might also be needed for a local PCx Docking Station and connection to an interface.

Network

Click the **Enable network communications** box to check it and enable network communications.

The default TCP service port assignments are listed in the Network tab page. If not using the default ports, click the port and type in the new assignment. Port numbers must be unique and in the range of 1024 to 65535.

Note: If a PCx Docking Station is sharing the ethernet port with an i-STAT Downloader, the PCx port assignment is made in QC Manager.

Interface

The appropriate interface protocol and the types of records to be sent to another data management system are selected in the Interface tab page. This configuration will typically be done by the interface provider.

Select the desired primary interface protocol. Then select the result types to be sent to the interface.
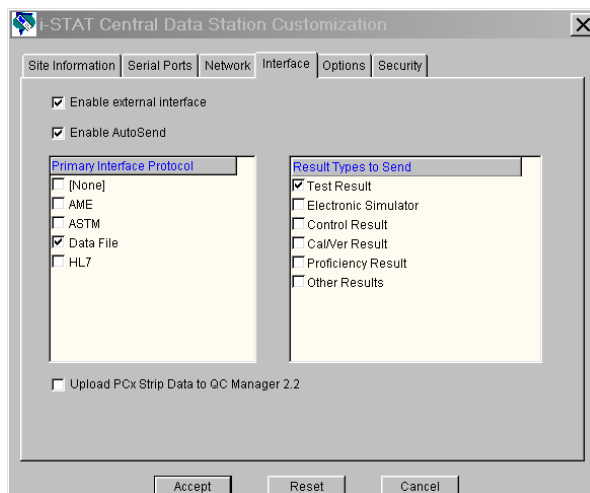
Primary Interface Protocol Choices	Explanation	Which Result Type(s) May be Transmitted
None	Indicates no primary protocol in use. Select when no external interface is used and PCx glucose test strip data is to be uploaded to QC Manager 3	N/A
AME	Automatic Manual Entry – Installed by Abbott Point of Care Inc.	1. Test Result 2. Electronic Simulator 3. Control Result 4. Cal/Ver Result 5. Proficiency Result
ASTM	Data Transmission conforms to ASTM E1381-95 and ASTM E1394-97	Patient Test Results ONLY
Data File	Formats the CDS for third-party use.	1. Test Result 2. Electronic Simulator 3. Control Result 4. Cal/Ver Result 5. Proficiency Result
HL7	Data transmission conforms to HL7 (version 2.4) and is based on the CIC Observation Reporting Interface distributed by the National Committee for Clinical Laboratory Science in the USA under Document POCT-1-A. This option is installed by Abbott Point of Care Inc.	Patient Test Results ONLY

Click **Enable external interface** box to check it and enable this function.

Click **Enable AutoSend** box to check it and enable this function. When AutoSend is enabled, new records will be automatically sent from the Central Data Station to another data management system whenever they are received by the Central Data Station. Checking this box will cause the CDS program to start up with AutoSend enabled on startup. AutoSend can be temporarily enabled/disabled from the CDS program as well. Records can also be sent manually from the Data Viewers.

When MediSense Precision PCx glucose test strips are being run on the i-STAT 1 Analyzer, the glucose test strip data can be made available to QC Manager data management program. Click the **Upload PCx Strip Data to QC Manager 2.2** box to enable this function.

Options

Confirmation message on exit: When this option is enabled, a confirmation message is displayed prior to exiting the CDS program.

Enable use of IR Link IDs: When enabled, the IDs programmed into the IR Links are used in determining the download location of the results instead of the actual serial port or IP address. To use this function, all IR Links must be of the self-identifying type. This option is not typically used but is available in case the functionality is needed.

Accept previously deleted records: When disabled, this option prevents previously deleted records from being stored when re-transmitted to the Central Data Station.

Monitor refresh: The status reports in the Download and Interface Monitors will be updated after the period of inactivity specified.

Maximum diagnostic files: Diagnostic files contain information that can be useful in troubleshooting cartridge problems. The default number is 100 and is changed at the request of a Customer Support representative.

Data Viewers: Selecting **Save method selection on exit** will cause each Data Viewer to save whichever method was selected when the viewer is closed or the **Exit** button clicked. The next time the viewer or CDS software is opened, the saved method will be displayed. When **Manually choose method before viewer opening** is selected, the user will be prompted to choose a method before a data viewer is opened.

Automatic Database Backup: When enabled, the CDS database files will be backed up to the selected location at the time of day entered. Should there be a malfunction resulting in the corruption of the database, a Customer Support representative may be able to retrieve the lost data from the backup copy. Each backup replaces the previous one. Backup time depends on the size of the database but usually does not take longer than 15 minutes.
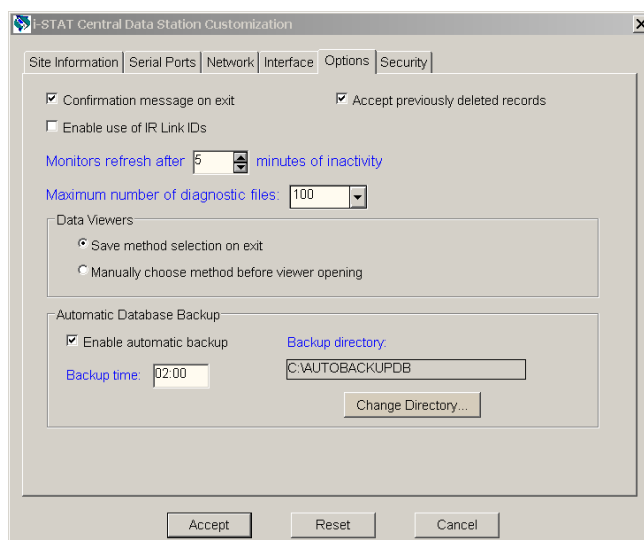
Security

The security features allow for the creation of security profiles providing different levels of access to various areas and functions of the CDS application. Individual users can then be assigned to a security profile, and then choose their own individual CDS log-on password. The system also has capabilities for manual and automatic logoffs.

The security features should only be activated by the administrator of the System; i.e. the person ultimately in charge of the CDS who will be creating the security profiles and assigning users to them.

The security features can be activated by performing the following steps:
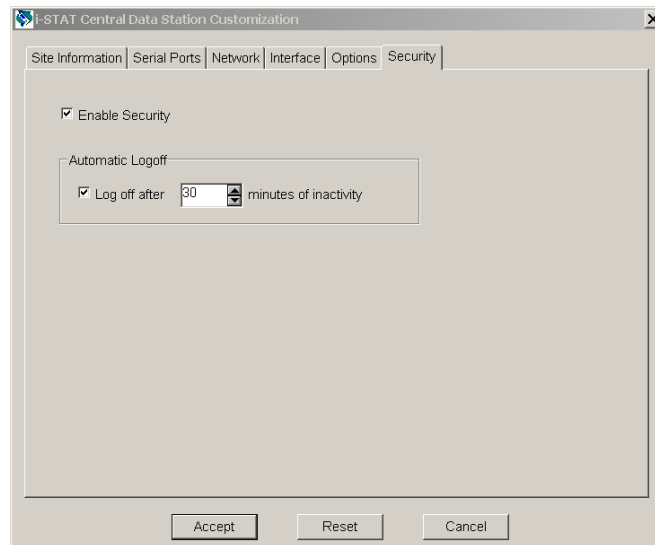
1. Check the box next to "Enable Security".

2. After enabling security, the user also has the option of selecting an inactivity interval after which the CDS will log off the current user. Simply click on the "Log Off" box and use the up/down arrows to choose the desired log off interval.

3. Click **Accept** at the bottom of the window.

4. A password dialog will then appear asking for a User Name and a Password. Type the User Name of **admin**, and the password **istat**. Then click on **OK**.

5. Another dialog box will appear prompting you to change your password. Note: Abbott Point of Care Inc. recommends changing the default password.
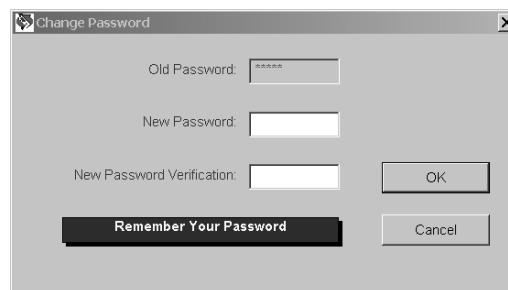
6. Type in a New Password of your choosing in the space provided. Then retype that same password on the New Password Verification line and click **OK**. This will automatically bring you to the CDS application.

INTERFACE PROGRAM CUSTOMIZATION
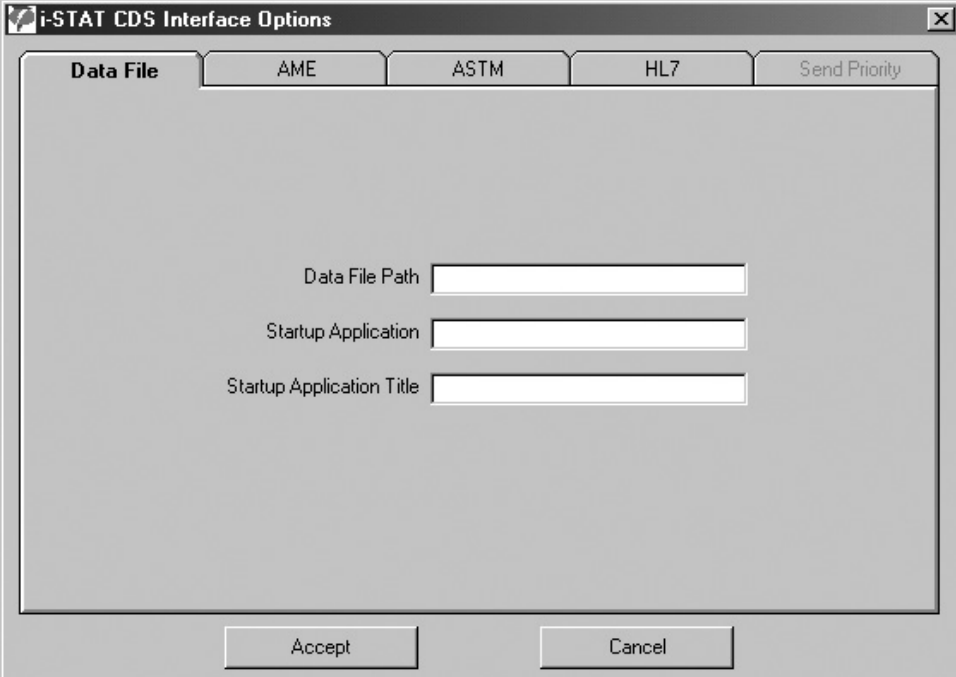
Overview
The Central Data Station can output results to an external computer system such as an LIS or HIS. The Central Data Station also provides a function that, when enabled, will also transmit all of the Precision PCx results generated on the i-STAT 1 Analyzer to QC Manager so they can be managed as part of the overall Blood Glucose Testing program.

The Central Data Station needs to be customized for the interface type using the procedures below. Tabs are presented for the options available. Each tab represents a protocol that the Interface Component of the CDS supports. Depending on the particular installation, one or more of these will be used.

Procedure
Exit the CDS application. Access the Run dialog box by clicking **Start** ⇨ **Run…** Type **c:\istat32\bin\interface32.exe** at the **Open:** prompt, then click **OK**. If **Run…** is not on the Start menu, double click the **Command Prompt** shortcut. At the C:\> prompt in the window that opens, type **c:\istat32\bin\interface32.exe** and press **Enter**. Click **File** ⇨ **Options**. The following screen will be displayed.

These tabs are used by the interface provider to configure the interface Component of the CDS for the protocol that will be used.

Send Priority
This function will prioritize the queue of results in the CDS database being processed by the Interface Component of the CDS program. This capability can be used by the interface provider to prioritize handling of results from one location over another.

Procedure

1. The CDS program must be running and the external interface must be enabled.

2. Double click the i-STAT interface icon in the system tray (next to the clock in the lower right hand corner of the screen) to open the interface program's main screen.

3. Click **File** ⇨ **Options**...

4. Click the **Send Priority** tab. (The other tabs will be available for viewing only.)

5. Click the Location/Method line to prioritize.

6. Right click under the **Send Priority** column and select the priority: Normal, High, Very High, from the drop down list.

7. Click **Accept** to finish.

i-STAT CDS Interface Options

Data File	AME	ASTM	HL7	**Send Priority**

LOCATION	METHOD	SEND PRIORITY
NICU	i-STAT	High
ICU	i-STAT	Normal
CVOR	i-STAT	Normal
ED	i-STAT	Very High
NICU	Precision PCx	Normal
ICU	Precision PCx	Normal
CVOR	Precision PCx	Normal
ED	Precision PCx	Normal

Accept   Cancel
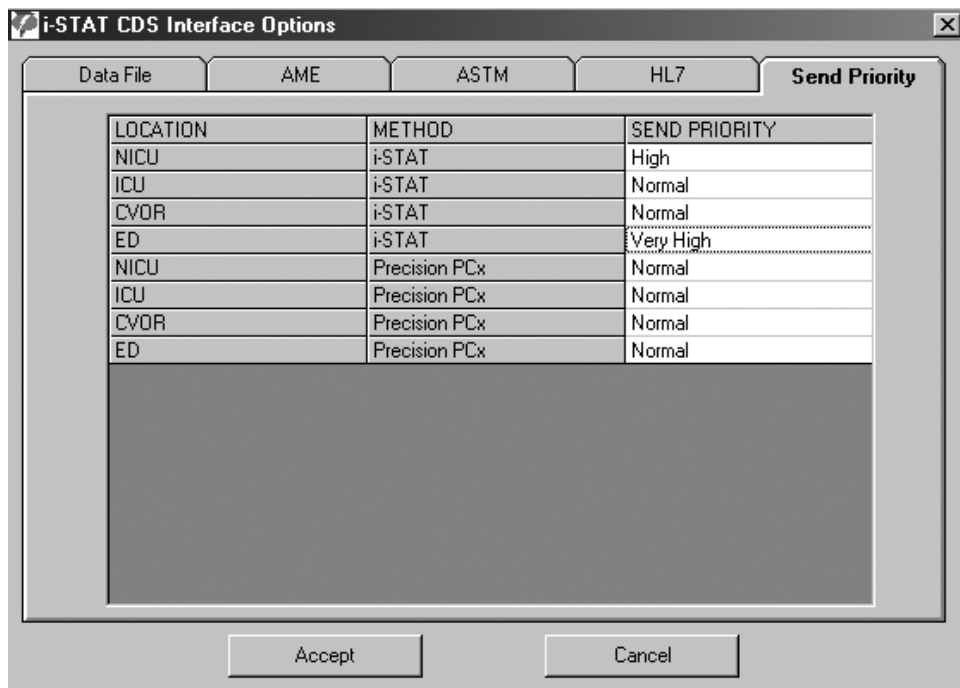
OVERVIEW OF THE CENTRAL DATA STATION PROGRAM

The Central Data Station (CDS) software includes the following point-of-care testing process management functions:

- Managing Instruments
- Managing Operators
- Managing Inventory
- Managing Policy Compliance
- Monitoring Operator Competence
- Reviewing Patient and Quality Results

- Managing Analyzer Customization Profiles
- Maintaining Database Contents and Size
- Monitoring External Interface Activities
- Monitoring Analyzer Download Intervals
- Managing LIS entry exceptions

These functions are listed under the main menu option in four main groupings: monitors, viewers, workspaces and reports.

Central Data Station Software Function Overview and Toolbar Buttons

 Monitor

 Download

 Interface

 Administration Tools (Workspaces)

 Instrument/Location

 Operator

 Database Maintenance

 Inventory

 Customization

 User Administration

 Data Viewer

 Results (patient)

 QC Codes

 Simulator

 Unsent Records

 Control Results

 Calibration Verification

 Proficiency Tests

 Report

 Reagent Management

 Method Competence

 Method Compliance

ADMINISTRATION TOOLS

Overview   Administration Tools include Workspaces for Instruments and Locations, Operators, Database Maintenance, Inventory, Customization, and User Administration.

INSTRUMENT AND LOCATION WORKSPACE

Overview   This workspace is used to:

- assign names to download locations,

- assign instruments to locations,

- configure the reporting and monitoring options for each instrument, and

- set required download intervals for each location.

The following sequence of tasks is used to set up the Central Data Station's management function for instruments:

1. Assign Location Names to Location Codes. Location Codes are the physical port addresses for the download devices.

2. Assign Instruments to Download Locations.

Locations
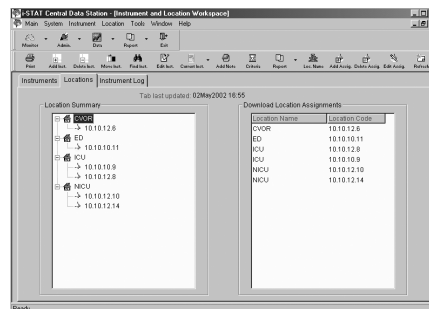
❑   Edit Location Name

The location name can be changed from a letter/number code to the name of a nursing unit, department, site, etc.. Up to 17 characters can be used to identify a location. Click **Location ⇨ Edit Location Name...** in the menu or click **Loc. Name** in the toolbar.

Note: Interface logic should be considered before editing.

❑   Add New Download Location Assignment

Download locations can be added manually.   Click **Location ⇨ Add Download Location Assignment…** in the menu or click the **Add Assig.** in the toolbar. Download locations will also be added automatically when a transmission is received from a download device with a location that is not already on the list. The name assigned is A_xx, where xx is the download device's IP address or serial port. This name can be changed as described under **Edit Download Location Assignment**.

To assign instruments to a location without a download device, enter a Location Name or another descriptive word as the Location Code.

❑   Delete Download Location Assignment

Click **Location** ➪ **Delete Download Location Assignment...** from the menu or click **Delete Assig.** in the toolbar.

❑   Edit Download Location Assignment

Click **Location** ➪ **Edit Download Location Assignment...** from the menu or click **Edit Assig.** in the toolbar.

Instruments

Once physical download locations have been given location names, the Instruments tab page will be the focus of management activities.
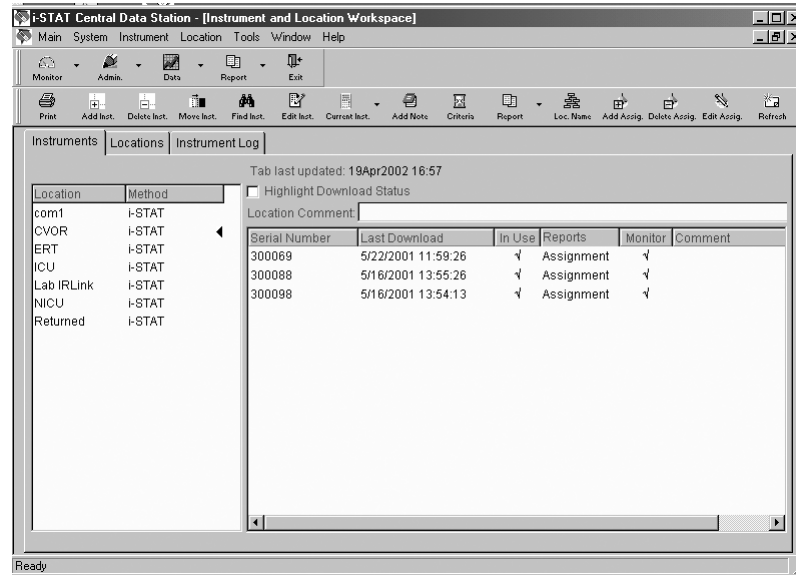
Location: Instruments are assigned to locations. This assignment is made when an instrument is manually added in the Instruments page or when an instrument downloads to the Central Data Station for the first time.

Method: The CDS is designed to accept results from any instrument that can be downloaded to the CDS program. The i-STAT method in the Instrument window refers to the i-STAT Portable Clinical Analyzer, the i-STAT 1 Analyzer (both i-STAT cartridge and MediSense Precision PCx and PCx Plus Glucose Test Strips) and the Philips Blood Analysis Module.

Clicking a Location/Method on the left side of the window will list the status of all instruments for that location and method in the right side of the window. A ◄ symbol indicates which location and method has been selected.

Highlight Download Status: Checking this box will highlight locations with instruments that have exceeded the required interval for downloading as well as noncompliant instruments within the location selected.

❑   Add Instrument

The Add instruments window is used to add an instrument to the system. Click **Instrument** ➪ **Add...** from the menu or click **Add Inst.** in the toolbar. Select a method from the drop down list.

Note: If using the i-STAT 1 Analyzer for cartridge and/or test strip runs, select i-STAT as the method.

Select a location from the dropdown list. If the location is not listed, add the location using the instructions under Add New Download Location Assigment. If the location does not have a download device associated with it, such as an instrument used for transporting patients, a location name can be typed in. (In this case the Location Code on the Locations tab page will be SYSCODExxxxxx.) Up to 17 characters can be used.

There are two options for Download Result Reporting, both of which apply to the i-STAT PCA, i-STAT 1 Analyzer, and the Philips Blood Analysis Module:

1. **Always report location as this assignment:** The results from this instrument will appear with the location of the instrument's assignment regardless of the download device used to transmit the results. This option is useful when an instrument is assigned to a functional group that may download from various areas in the institution. The instrument will be designated "Assignment" under the Reports column in the Instruments tab page.

2. **Report location as download location:** The results from this instrument will appear with the location for the download device that was used to transmit results to the Central Data Station. The instrument will be designated "Download" under the Reports column on the Instruments tab page.

   If the instrument is not manually added to the list and it transmits to the CDS, it is automatically assigned to the location of the download device and is set to report "Download." If the download device location has not been manually added, a default location A_xx (B_xx, C_xx, etc.), where xx is the IP address or serial port of the download device, will be used.

There are two options for Download monitoring:

1. **Include in download monitoring:** Includes this Serial Number in download monitoring.

2. **Exclude download monitoring:** The download status of the instrument will not be reported by the Download Monitor. (Blood Analysis Modules and infrequently used or spare analyzers might be exempted from the Download Monitor report).

❑ Delete Instrument

Click the Location/Method for the instrument to be deleted and then the serial number of the instrument to be deleted. Click **Instrument** ➪ **Delete...** from the menu or click **Delete Inst.** in the toolbar.

❑ Move Instrument

Click the Location/Method for the instrument to be moved and then on the serial number of the instrument to be moved. Click **Instrument** ➪ **Move...** from the menu or click **Move Inst.** in the toolbar. Select the new location from the drop down list or type in a new location.

❑ Find Instrument

Click **Instrument** ➪ **Find...** from the menu or click **Find...** in the toolbar. Enter the serial number of the instrument and select the Method from the drop down list.

❑ Edit Instrument Comment

Click the instrument serial number, click **Instrument** ➪ **Edit Comment** from the menu or click **Edit Inst.** in the toolbar. Enter a comment of up to 16 characters.

❑ Change Current Instrument Setttings

Reporting: Click the instrument serial number. Click **Instrument** ➪ **Current Instrument** ➪ **Change Reporting** from the menu or click the down arrow next to **Current Inst.** and then **Reporting** in the toolbar to toggle between **Download** and **Assignment**.

In Use: Click the instrument serial number. Click **Instrument** ➪ **Current Instrument** ➪ **Toggle In Use** from the menu or click the down arrow next to **Current Inst.** and then **In Use** in the toolbar to check (in use) or un-check (out of use) the analyzer in the In Use column.

Instruments that are not checked "In Use" do not have a download criteria applied to them. You would use this for instruments you do not expect to be downloaded. When an analyzer that is not marked "in use" downloads, it is set back in use and the download criteria is applied.

Monitoring: Click the instrument serial number. Click **Instrument** ➪ **Current Instrument** ➪ **Change Monitoring** from the menu or click the down arrow next to **Current Inst.** and then **Monitoring** in the toolbar to check or un-check the analyzer in the Monitoring column.

❑ Add Instrument Note

Click **Instrument** ➪ **Add Note...** from the menu or click **Add Note** in the toolbar. A note of up to 50 characters can be entered. The note will appear as a Log Entry in the Instrument Log tab page.

❑ Change Download Monitoring Criteria

Compliance to download policy can be monitored by the CDS program. Click on the Location/Method. Click on **Instrument** ➪ **Download Criteria...** from the menu or click **Criteria** in the toolbar. Enter the required download interval. An interval of up to 1000 hours is allowed.

Compliance with the criteria can be observed by checking the Highlight Download Status check box or by going to the Download Monitor. Individual Download criteria can be set for each location and method pair.

Note: The i-STAT 1 Analyzer can also be customized either to warn the end users that a download is required or to lockout end users if the time for a download has been reached or exceeded. The download criteria for analyzers and for the CDS monitor should be selected to make sense.

❑ Instrument and Location Summary

The Instrument and Location Summary provides a report of the current instrument assignments and the last download for each instrument. Click **Main ⇨ Open Report ⇨ Instrument Summary** from the menu or click the down arrow next to **Report** and then **Summary** in the toolbar. Summaries can be viewed and printed by:

- This method and location only (location and method selected with ◄ symbol)

- This method, all locations (method selected with ◄ symbol)

- All methods, all locations

Instrument Log

The Instrument Log tracks all changes made in the Instruments tab page. Additional comments can be added to the log by clicking **Add Note** in the toolbar.

❑ Date Range...

Data can be viewed within a user defined default range or by a manually entered range.

❑ Delete...

The **Delete** button allows selected or all entries within the date range selected to be deleted.

To print the log press the **F2** key or select **Print** from the Main menu or toolbar.
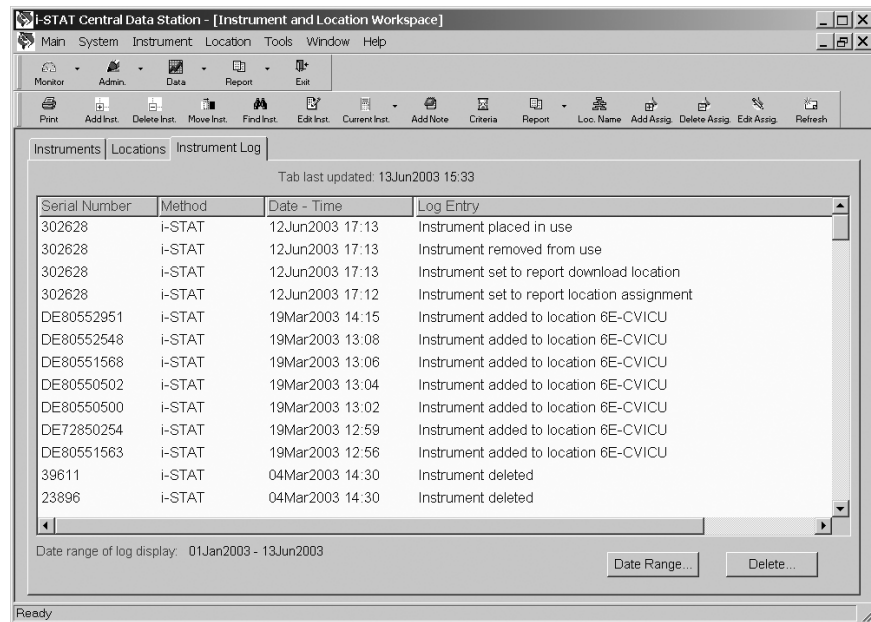
Overview

This workspace is used to:

- Record operator names and identification numbers

- Record certification dates and certification expiration dates

- Assign operators to departments

- Add comments

When the i-STAT 1 Analyzer is customized to use the operator list created here, the analyzer can be customized to warn or lockout operators if they are not on the list or their certification has expired.

Operators

Operators are listed by Department and Method as indicated by the ◄ symbol. Operators are added to the operator list by department and by method.

When a record is received with an Operator ID that is not listed in any Department, the operator is placed in the "Unassigned" department.
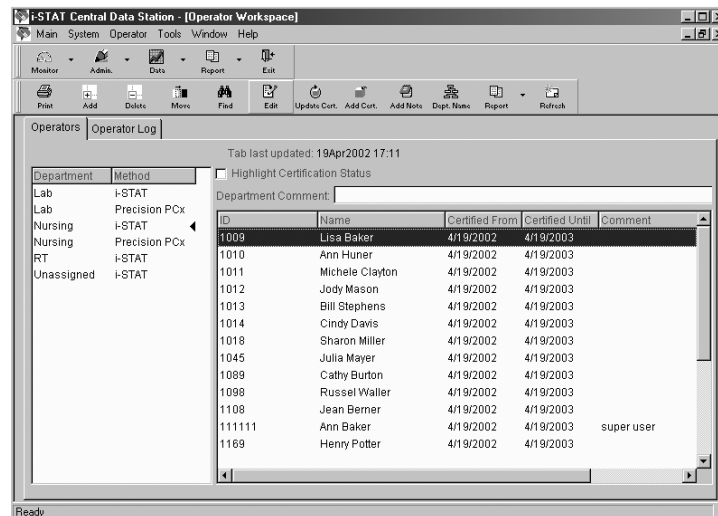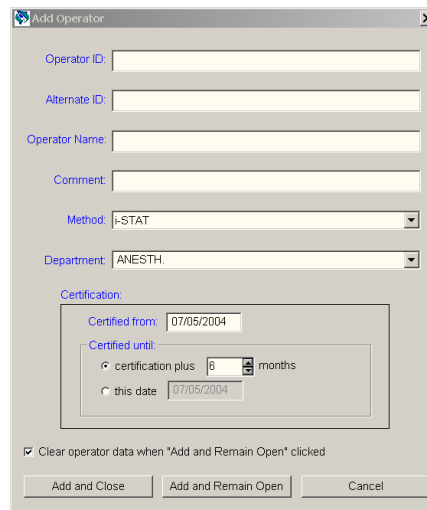
❑ Operator list edit in progress

When editing the operator list, check this box to delay updating i-STAT 1 analyzers until all editing is complete. When editing is complete, click the box to remove the checkmark. This box will appear when Serial or Network Communications are enabled, Customization is enabled and Use Operator List is enabled.
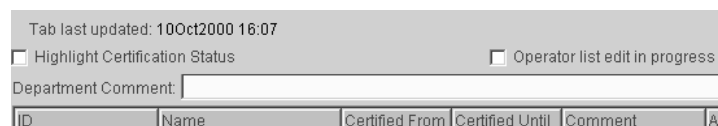
❑ Add Operator

This function is used to add new operators to the list of operators. Alternatively, operator lists can be imported (see Operator List Import at the end of this section). Click **Operator** ➪ **Add**... from menu or **Click** on **Add** in the toolbar.

Enter the ID number that the operator will enter into the analyzer on the Operator ID line. If a different ID number is used to access the LIS, this number should be recorded on the Alternate ID line. An Operator Name of up to 40 characters can be entered. A comment of up to 16 character can be added. If operators are to be certified for more than one method, such as for the i-STAT cartridge and the PCx glucose test strip, certify each operator for one method and use the **Add Cert.** toolbar button to certify all applicable operators at one time for the method. To add the first operator to a department, type the department name (up to 10 characters). Once a department has been added, it can be selected for additional operators from the drop down menu.

Check the **Clear Operator data when "Add and Remain Open" clicked** box to specify whether or not the operator information fields should be cleared when the Add and Remain open button's clicked.

❑ Delete Operator

Select the operator or operators. Click **Operator** ➪ **Delete...** from the menu or click **Delete** in the toolbar to delete the operator or operators. When the last operator from a department is deleted, the department is removed from the system.

❑ Move Operator

Select the operator or operators. Click **Operator** ➪ **Move...** from the menu or click **Move** in the toolbar, and select a new department from the drop down list. If the department is not in the list, type in the new department name.

❑ Find Operator

Click **Operator** ➪ **Find...** from the menu or click **Find** in the toolbar, select the method for which the operator is certified, and type in the operator ID. A box will appear around the found operator.

❑ Edit Operator Data

Click the operator. Click **Operator** ➪ **Edit** from the menu or click **Edit** in the toolbar. The operator ID, name, comment and alternate ID can be edited.

❑ Update Certifications

Select the operator or operators. Click **Operator** ➪ **Update Certification...** from the menu or click **Update Cert.** in the toolbar and complete the Update Certification form.

❑ Add Certification

The Add Certification button allows operators who are certified for one method to be certified for another method without having to complete a new Add Operator form. Highlight the operator or operators in the Operator tab window that are to be certified for another method. Click **Operator** ➪ **Add Certification...** from the menu or click the **Add Cert**. button on the toolbar. Select the other method for which these operators are to be certified, then specify the certification dates.

❑ Add Note

Click the operator. Click **Operator** ➪ **Add Note...** from the menu or click **Add Note** in the toolbar. An Operator Log Note of up to 50 characters can be typed.

❑ Edit Department Name

Click the department name to edit. Click **Operator** ⇨ **Edit Department Name** from the menu or click **Dept. Name** in the toolbar. The Unassigned designation cannot be changed.

❑ Operator and Certification Reports

Click on the down arrow next to **Report** in the Operator Workspace toolbar and click on **Summary** or **Expiration**.

Operator Summary: Summaries of operators can be viewed and printed by:

- This method and department only (department and method selected with ◄ symbol)

- This method, all departments (method selected with ◄ symbol)

- All methods, all departments

   The reports include operator IDs, operator names, certified from date, certified until date, comments, a checkmark if certification has expired and the operator's alternate IDs grouped by department and method.

Operator Certification Expiration: This report allows the certification status of operators to be viewed.

Operator Log

The Operator Log tracks changes made and "Add Note" entries made in the Operator tab page. The **Date Range...** button can be used to specify a time period to be viewed and the **Delete...** button to delete entries. To print the log press the **F2** key or select **Print** from the Main menu.

ID	Method	Date - Time	Entry
2142	i-STAT	5/22/2006 14:31:23	Certification set from 5/22/2006 to 10/22/2006
12345	i-STAT	5/22/2006 14:31:15	Certification set from 5/22/2006 to 5/22/2007
004599804	i-STAT	5/22/2006 14:31:03	Certification set from 5/22/2006 to 1/22/2007
1345	i-STAT	5/22/2006 14:30:41	Certification set from 5/22/2006 to 1/22/2007
035	i-STAT	5/22/2006 14:30:33	Certification set from 5/22/2006 to 11/22/2006
1204	i-STAT	5/22/2006 14:30:23	Certification set from 5/22/2006 to 11/22/2006
2142	i-STAT	5/22/2006 14:30:02	Operator moved from Unassigned to Laboratory
1345	i-STAT	5/22/2006 14:29:52	Operator moved from Unassigned to CCU
12345	i-STAT	5/22/2006 14:29:24	Operator moved from Unassigned to Laboratory
1204	i-STAT	5/22/2006 14:29:13	Operator moved from Unassigned to CCU
035	i-STAT	5/22/2006 14:29:04	Operator moved from Unassigned to CCU
004599804	i-STAT	5/22/2006 14:28:24	Operator moved from Unassigned to Laboratory

Operators | Operator Log

Tab last updated: 22May2006 14:32

Date range of log display: 15May2006 - 22May2006

Date Range...   Delete...

OPERATOR LIST IMPORT

This function in the Operator Workspace on the CDS5 allows an operator list to be imported from a text file. To access this function, click on **Main ⇨ Open Administration Function ⇨ Operator** from the main menu to open the Operator Workspace. Select **Operator ⇨ Import List...** from the main menu to open the Import Operator List window. This window is used to describe the format of the text file containing the list to be imported into the CDS.

Import List Instructions

1. Under **Fields in text file:**, use the mouse to drag and drop the field names so they match the order in which the fields appear in the text file containing the list to be imported. If a field does not appear in the text file, drag it to the **Available fields:** list. If the text file contains a field that should be ignored, drag a **SkipField(x)** field to the **Fields in text file:** list to mark where that field appears.

2. Fields in the text file containing the list to be imported must be separated by a comma or other delimiter character. Specify the separator in the **Delimiter character** box.

3. If a qualifier character is used to enclose the data contained in each the field in the text file containing the list to be imported, select this character from the **Text qualifier:** list.

4. If the first line of the text file is a header line listing the names of the fields in the text file containing the list to be imported, click **Skip first line of file (file contains headers)**. The import function cannot process header lines.

5. If all operators in the text file containing the list to be imported are to be certified for one method, click **Assume a test method for all operators** and select **i-STAT** for cartridge testing or **Precision PCx** for the MediSense Precision PCx or PCx Plus Glucose Strip testing on the i-STAT1 Analyzer. If this option is selected, the text file does not need to contain a **Method** field. If this option is selected and the text file does contain a **Method** field, its contents will be ignored

6. If all operators will be certified from the same date, click on **Assume a certification start date for all operators** and enter the start date. If this option is selected, the text file does not need to contain a **Certified from** field. If this option is selected and the text file does contain a **Certified from** field, its contents will be ignored.

7. If all operators are to be assigned to the same department, such as Nursing or Perfusion, click on **Assume a single department for all operators** and enter or select the department from the drop down list. If this option is selected, the text file does not need to contain a **Department** field. If this option is selected and the text file does contain a **Department** field, its contents will be ignored

    Example from list to be imported:

    "ICU", "12345", "Smith, Judy", "none", "98765", "i-STAT", "2001-08-08", "2002-08-08"

8. Click **Select File…** and select the name of text file containing the list to be imported.

9. Click **Import File** to import the list from the text file.

Note: operator data that already exits in the CDS5 database takes precedence over any data imported from a text file.

Export List After a list has been imported or created, it can be exported for backup purposes.

DATABASE MAINTENANCE
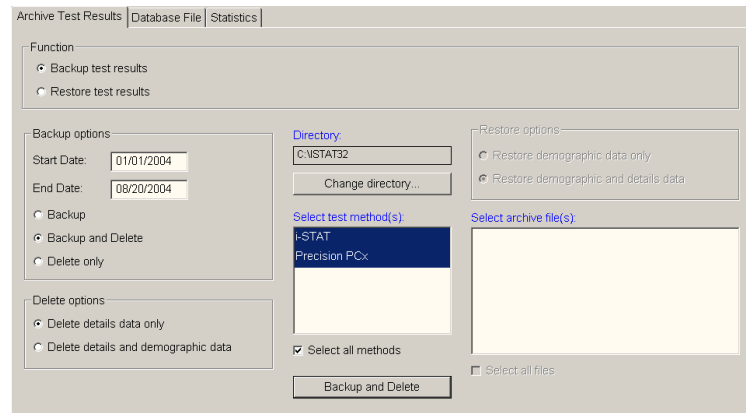
Overview
This workspace allows the database to be backed up, deleted and restored. A "Statistics" tab page also allows users to view a summary page of Result Types contained in the database.

Archive Test Results
Backup test results: This function allows test results to be backed up onto a disk, CD or other directory. (Note: a 1.44MB disk will only store about 1000 test records.)

1. Click on **Main ⇨ Open Administration Functions ⇨ Database Maintenance.**

2. After the workspace opens, click the **Archive Test Results** tab.

3. Click the **Backup** test results radio button.

4. Specify a date range for the function.

5. Select a Backup Option: **Backup**, **Backup and Delete**, or **Delete only**.

6. If an option that includes Delete is selected, then select a Delete Option: **Delete details data only** or **Delete details and demographic data**. Details data includes:

    • Original Operator and Patient ID

    • Patient Name

    • LIS order number

    • Sent status

    • Analyte values

    • Extra data

    Demographic data can be used to generate reports. Demographic data includes:

    • Test type (test result, simulator, proficiency,...)

    • Test panel (such as EC8+, CG8+, PCx Glucose)

    • Test Method (i-STAT, Precision PCx...)

    • Patient ID

    • Operator ID

    • Test date/time

- Location

- Comment

- Interface comment

- Serial number

- Department

7. Select a Directory.

8. Select a method or methods to back up or click **Select all methods**.
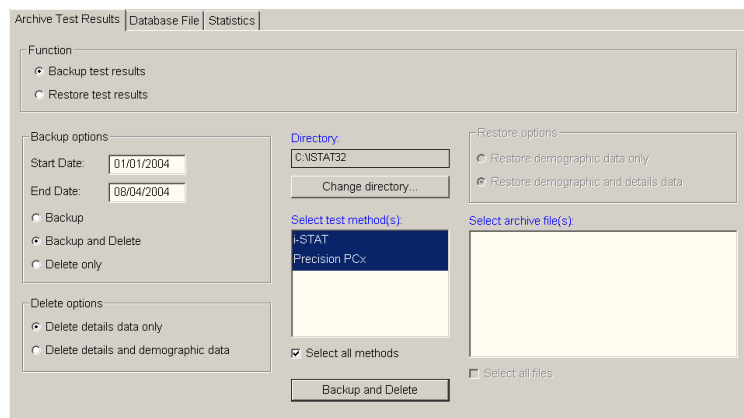
9. Click the button marked **Backup** or **Backup and Delete** and follow the prompts.

Note: When results are being deleted as part of a backup and delete or a delete only operation, the deletion can be cancelled. Simply click on the **Cancel** button to stop the operation. Once the **Cancel** button is clicked, depending on the amount of data being deleted and the size of the database, there may be a significant lag time of a few minutes before a dialog box appears indicating that the deletion has been paused, asking you to select one of three options:
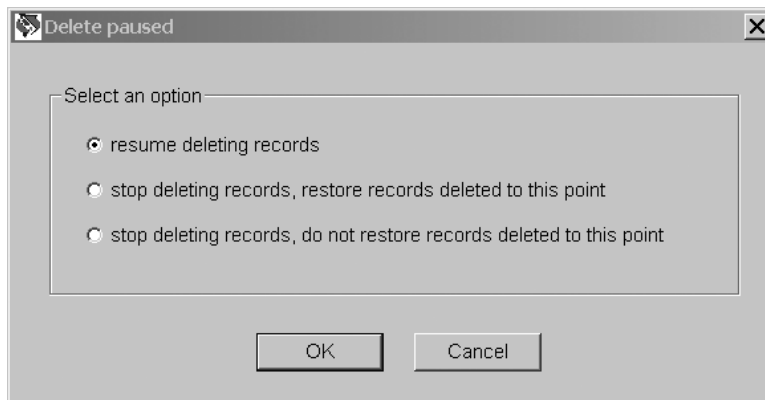
The reason for the lag time is that the program needs to complete whatever portion of the deletion operation it was performing when the **Cancel** button was clicked before it can display the dialog box. Once the dialog box is displayed, simply click on the desired radio button and then click **OK**.

Restore test results: This function allows test results that have been deleted from the CDS but backed up elsewhere to be restored to the database.

1. Click on **Main ⇨ Open Administration Functions ⇨ Database Maintenance**.

2. Insert disk or CD where files are located.

3. Click the **Restore test results** radio button.

4. Select the directory for the stored results.

5. Select the method or methods to be restored.

6. Select a restore option: **Restore demographic data only** or **Restore demographic and details data**. (Demographic data can be used to generate reports.)

7. Select the files to be restored or select all files.

8. Click the **Restore** button.

Database File

Backup Database File: This function allows the user to manually perform the same operation that occurs when the automatic database backup occurs. It creates a complete backup of the database file to the specified drive/directory.

Compact Database File: When the backup and delete or delete only functions are executed, the deleted data is removed from the database but the disk space the data occupied in the database file is not. The compaction function creates a new copy of the database with the excess space removed, creating a smaller, better organized and, therefore, more responsive database. If CDS functions such as opening or refreshing a data viewer grow noticeably less responsive over time, compaction of the database may help. It is recommended that compaction function be executed at least once a year.

Statistics

A "Statistics" tab page allows users to view a summary page that lists:

1. The total results in the database,

2. The date and time of the oldest result in the database,

3. The date and time of the newest result in the database, and

4. A breakdown of the total results in the database by Result Type and Method.

Archive Test Results	Database File	Statistics

Total Results in Database: 86172

Oldest Result in Database: 5/27/2001 12:11:00

Newest Result in Database: 12/18/2003 10:06:15

Result Type	Method	Total
Test Result	i-STAT	56406
Electronic Simulator	i-STAT	20981
Quality Check Code	i-STAT	3222
Control Result	i-STAT	1024
Cal/Ver Result	i-STAT	604
Proficiency Result	i-STAT	79
Test Result	Precision PCx	914
Quality Check Code	Precision PCx	56
Control Result	Precision PCx	1111

Details…

Selecting an individual Result Type and then clicking on Details allows you to view a similar statistical breakdown for that particular Result Type:

1. The total number of that particular Result Type in the database,
2. The date and time of the oldest result of that type in the database,
3. The date and time of the newest result of that type in the database,
4. A breakdown of the number of this particular result type that have been sent successfully (Yes), unsuccessfully, or not sent at all (No) to the LIS/HIS. Note: a listing in this window for "Not Available" indicates that there are records of this type in the database where the details data have been deleted, so the application cannot determine whether that particular record was sent or not.

i-STAT / Test Result

Total Results in Database: 56406

Oldest Result in Database: 5/27/2001 12:11:00

Newest Result in Database: 12/8/2003 11:36:57

Sent	Total
Not Available	34907
No	24
Unsuccessful	2225
Yes	19250

Close
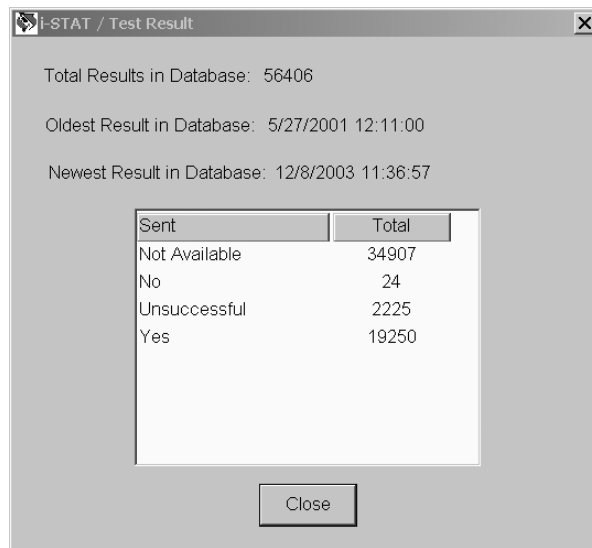
Overview

The Inventory Workspace is organized under five tabs with the following functions:

- Stock: define reorder triggers, view and edit inventory

- Distribution: track items distributed from central stock to different locations

- Orders: track pending and received orders, view reports on received items

- Items: define inventory items

- Inventory log: view a log of major user actions
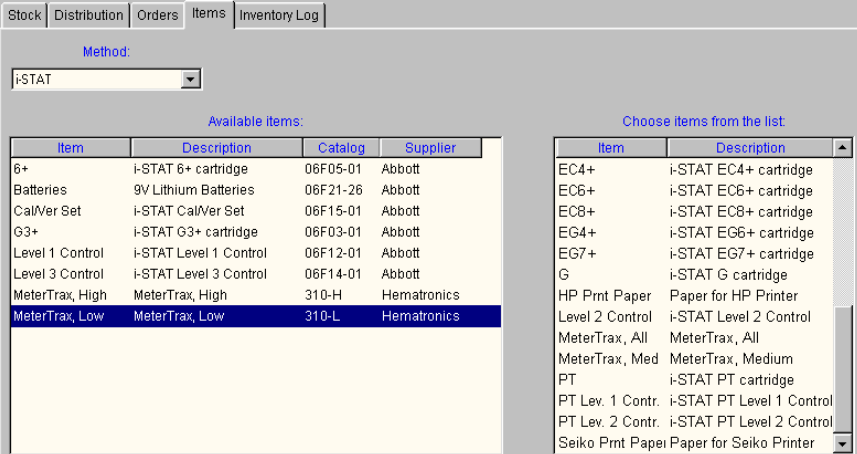
Populate the Items tab first, followed by the Stock tab where current inventory should be entered and reorder triggers defined.

Items

The Items tab is used to define the inventory items for the i-STAT System and other point-of-care tests.

To select an item available from i-STAT and its distributors, highlight the item in the **Choose items from the list** on the right side of the window, then click the arrow next to the **Add** button in the tool bar and click the **Selected** button. The item will move to the **Available items** list on the left side of the window.

To add an item not available from i-STAT and its distributors, click the arrow next to the **Add** button in the tool bar, then click the **New** button and complete the displayed information form.

Item	Description	Catalog	Supplier
6+	i-STAT 6+ cartridge	06F05-01	Abbott
Batteries	9V Lithium Batteries	06F21-26	Abbott
Cal/Ver Set	i-STAT Cal/Ver Set	06F15-01	Abbott
G3+	i-STAT G3+ cartridge	06F03-01	Abbott
Level 1 Control	i-STAT Level 1 Control	06F12-01	Abbott
Level 3 Control	i-STAT Level 3 Control	06F14-01	Abbott
MeterTrax, High	MeterTrax, High	310-H	Hematronics
MeterTrax, Low	MeterTrax, Low	310-L	Hematronics

Item	Description
EC4+	i-STAT EC4+ cartridge
EC6+	i-STAT EC6+ cartridge
EC8+	i-STAT EC8+ cartridge
EG4+	i-STAT EG6+ cartridge
EG7+	i-STAT EG7+ cartridge
G	i-STAT G cartridge
HP Prnt Paper	Paper for HP Printer
Level 2 Control	i-STAT Level 2 Control
MeterTrax, All	MeterTrax, All
MeterTrax, Med	MeterTrax, Medium
PT	i-STAT PT cartridge
PT Lev. 1 Contr.	i-STAT PT Level 1 Control
PT Lev. 2 Contr.	i-STAT PT Level 2 Control
Seiko Prnt Paper	Paper for Seiko Printer

To delete an item from the Available items list, highlight the item, then click the **Delete** button in the tool bar. If the item was selected from **Chose items from the list**, the item will be moved from **Available items** back to this list.

To edit information under the **Available items** list, click the **Edit** button in the tool bar.

Stock   The Stock tab includes both Inventory and Estimated Inventory statistics.

Inventory: The number of given items as counted and entered by the user. The inventory is automatically updated when new orders are received under the Orders tab.

Estimated Inventory: The number of i-STAT cartridges and MediSense PCx and/or PCx Plus glucose test strips as estimated by the workspace software. The initial Estimated Inventory is taken from the Inventory column. Every time a cartridge or glucose test strip result is transmitted to the Central Data Station software, the count of the estimated inventory decreases by 1. The Estimated Inventory is automatically updated when new orders are received under the Orders tab. The Estimated Inventory item count is adjusted to the Inventory count whenever the Inventory column is manually edited.
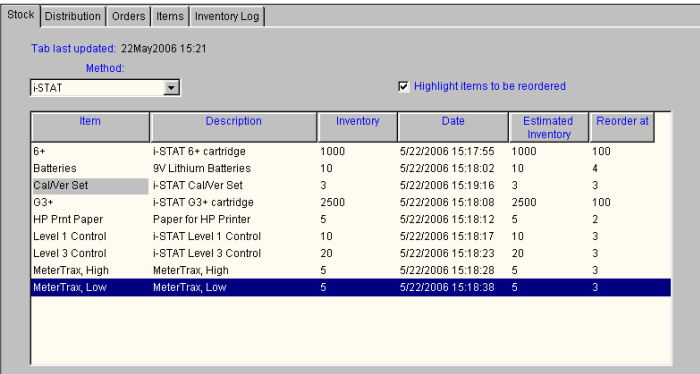
Startup Option   The items added under the Items tab will be listed under the Stock tab with **Inventory** and **Reorder** set to 0. There are two ways to populate the Inventory column.

1. Count current stock. Go to the Stock tab, click on the **Edit** button in the tool bar, and enter the current inventory. Lot numbers and Expiration dates will not be tracked for inventory entered by this method.

2. Count current stock along with lot numbers, expiration dates and locations. Go to the Order tab and enter and receive the POs for the existing stock. Go to the Stock tab and manually adjust the Inventory to the current stock count. (Alternatively, receive only the current stock count.) This option allows the user to take advantage of the lot number and expiration date tracking capabilities of the workspace.

Click on the Edit button on the tool bar and enter the reorder trigger numbers.

Click a check mark next to **Highlight items to be reordered**. Items that need to be reordered will be highlighted. (See CalVer Set in illustration below.) Reorders are highlighted based on the **Estimated Inventory**.

The inventory can be edited by highlighting the item and clicking the **Edit** button or by clicking the **Adjust Invent** button, selecting the item from the drop down menu, and adding or subtracting units. When the **Inventory** is edited, the **Estimated Inventory** is automatically made equal to the **Inventory**.

The **Estimated Inventory** for i-STAT cartridges and MediSense PCx glucose test strips will automatically begin updating with the next analyzer transmission. Click the **Refresh** button to update the workspace for transmitted data. Both the **Inventory** and the **Estimated Inventory** are updated automatically when orders are received under the Orders tab.

Periodically, the **Estimated Inventory** should be updated manually. This is necessary to account for other consumables as well as for cartridges and strips that are discarded before testing, such as expired inventory. Click the **Estim. Invent.** button in the tool bar to adjust the **Estimated Inventory**.

Orders

To record a new order, click on the **Add** button in the tool bar. Select the item from the drop down menu under **Item** and enter the quantity. Click the **Add Item** button to add another item or the **Delete Item** button to delete an item.

To enter information about a received order right away, click on the **Receive Order** button. To enter information about a received order later, click the **Order Pending** button.

To receive an item or to edit order information, click the **Edit/Receive** button in the tool bar. Highlight the PO Number and enter the **Order Details**.

Note: The lot number and expiration date are used in the Distribution tab. Therefore, PO, lot number and expiration date information for consumables in inventory should be entered here. The PO number field can accommodate up to 20 characters.
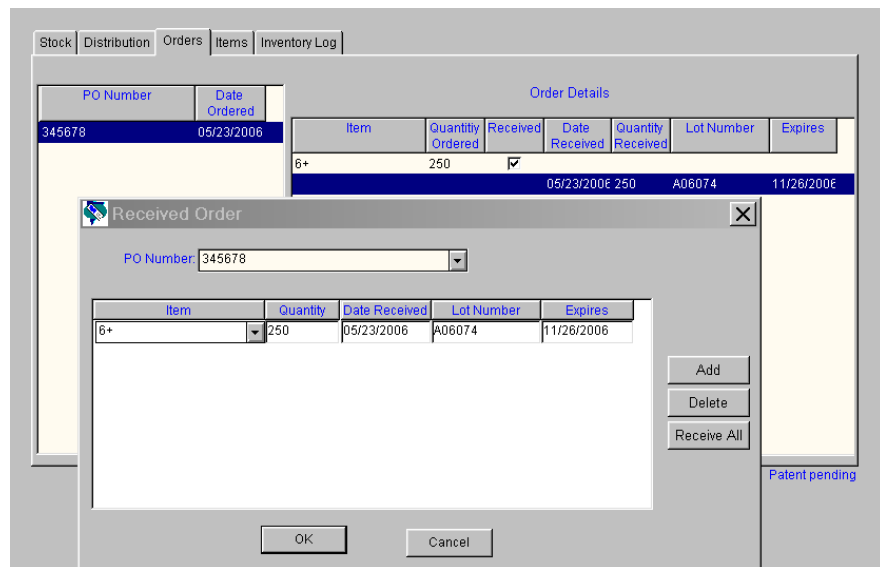
Click the **Add** Button to add another item or the **Delete** Button to delete an item. Click the **Receive All** Button to automatically enter items and quantities, as they were ordered.
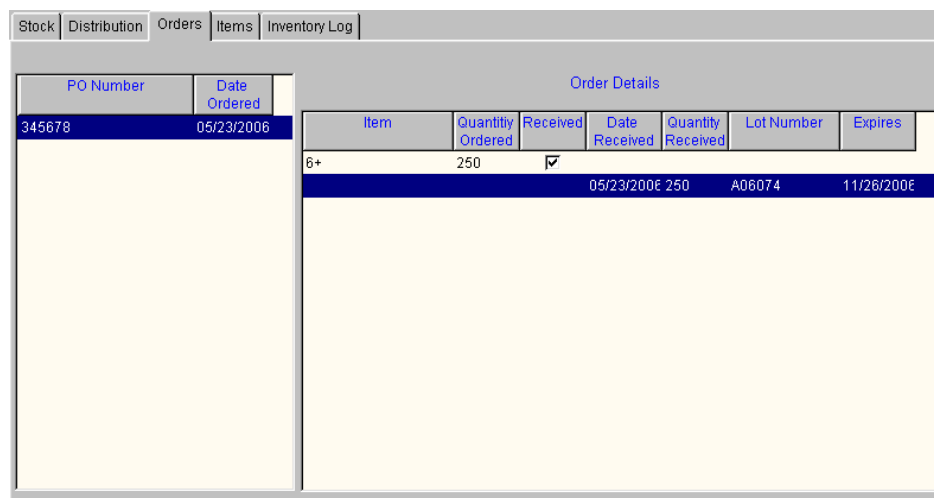
Use the **Delete** button on the tool bar to delete an order.

Use the **Find Lot** and **Find Next** buttons on the tool bar to find the PO associated with a received lot.
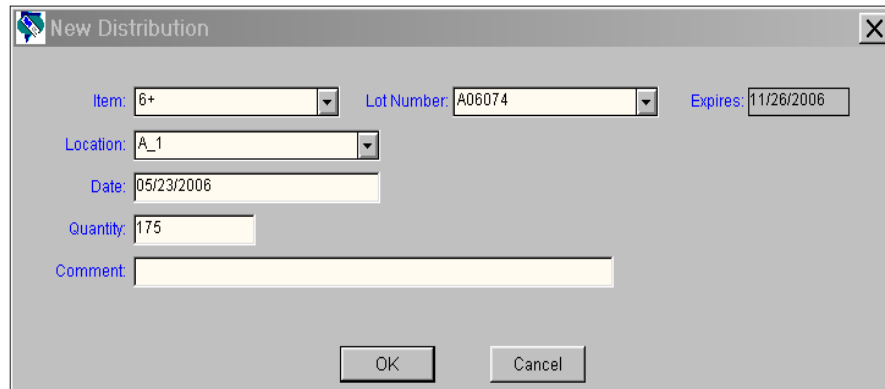
Use the **Delete Lot** button on the tool bar to delete a lot number that has expired or has been used up.

The **Report** button on the tool bar is used to view all received items by date range.

Use the **Add Note** button on the tool bar to add a note to the **Inventory Log**.
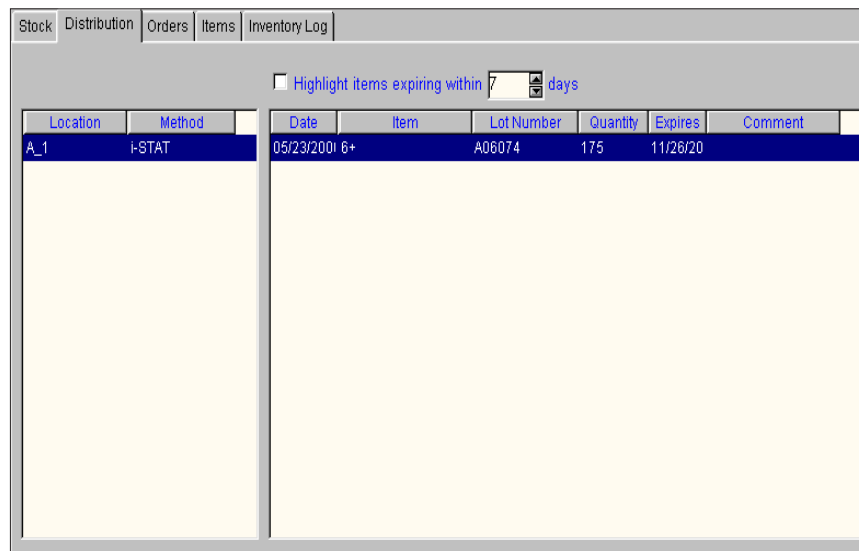
Distribution

Use the **Add** button in the tool bar to record the distribution of consumables. The Item drop down menu includes all consumables entered in the Items tab. The Location drop down menu includes all locations entered in the Instrument and Location Workspace. The Lot Number drop down menu includes lot numbers for the selected items received in the Order tab. The expiration date is entered automatically. A comment of up to 16 characters can be entered.

The Distribution tab will list each location with its consumables. Define an alert date and click a check mark next to **Highlight items expiring within xx days** to alert you to transfer stock to a different location where it can be used before its expiration date.

Use the **Delete** button on the tool bar to delete a distribution.
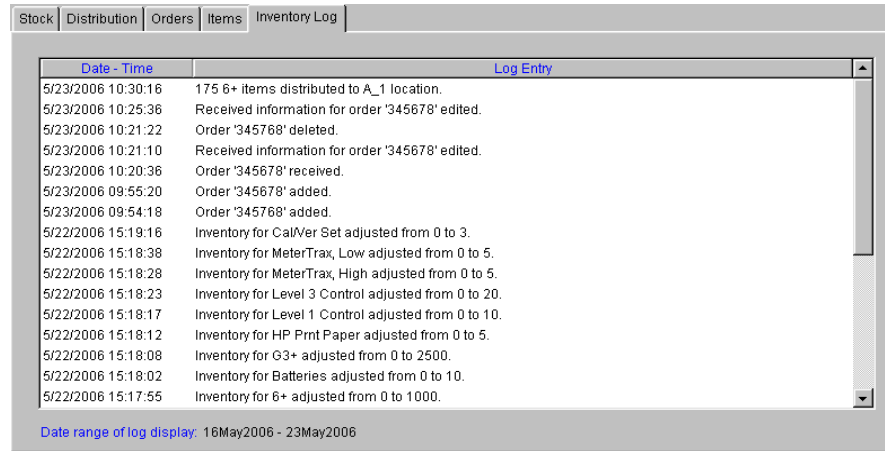
Use the **Transfer** button in the toolbar to move consumables from one location to another.

Use the **Find Lot** button to find a location where a consumable of a specific lot has been distributed. Click the **Find Next** button to find other locations for this lot.

Use the **Add Note** button to add a note to the Inventory Log.

Inventory Log

The Inventory Log documents each action taken in the Items, Stock, Distribution and Orders tabs. Click the **Date Range** button in the toolbar to select the a Default date range or a Start and End date for this report. Click the Delete button to delete entries in the log.

Date - Time	Log Entry
Stock	Distribution	Orders	Items	Inventory Log
5/23/2006 10:30:16	175 6+ items distributed to A_1 location.
5/23/2006 10:25:36	Received information for order '345678' edited.
5/23/2006 10:21:22	Order '345768' deleted.
5/23/2006 10:21:10	Received information for order '345678' edited.
5/23/2006 10:20:36	Order '345678' received.
5/23/2006 09:55:20	Order '345678' added.
5/23/2006 09:54:18	Order '345768' added.
5/22/2006 15:19:16	Inventory for Cal/Ver Set adjusted from 0 to 3.
5/22/2006 15:18:38	Inventory for MeterTrax, Low adjusted from 0 to 5.
5/22/2006 15:18:28	Inventory for MeterTrax, High adjusted from 0 to 5.
5/22/2006 15:18:23	Inventory for Level 3 Control adjusted from 0 to 20.
5/22/2006 15:18:17	Inventory for Level 1 Control adjusted from 0 to 10.
5/22/2006 15:18:12	Inventory for HP Prnt Paper adjusted from 0 to 5.
5/22/2006 15:18:08	Inventory for G3+ adjusted from 0 to 2500.
5/22/2006 15:18:02	Inventory for Batteries adjusted from 0 to 10.
5/22/2006 15:17:55	Inventory for 6+ adjusted from 0 to 1000.

Date range of log display: 16May2006 - 23May2006

CUSTOMIZATION WORKSPACE

Overview

This workspace is used to create profiles with site specific test characteristics for the analyzers. See the Customization section of this manual for details of items that can be customized and their default settings.
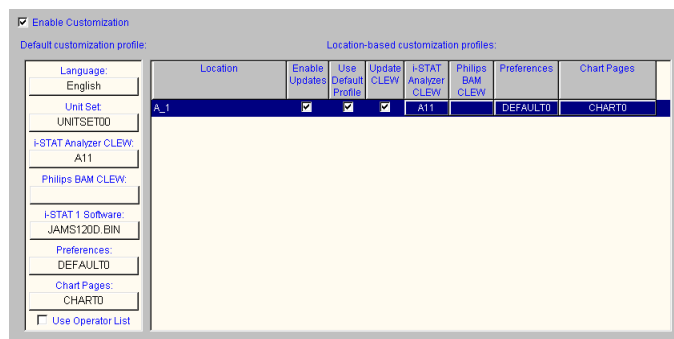
Password

The Customization Workspace is password protected. If the Security feature is disabled, the default password is **istat**. If the Security feature is enabled, the user uses the same password as their CDS application logon password. To change the password, select **Tools** and **Change Password** from the menu bar. A password from 3 to 8 characters can be used. Note: Abbott Point of Care Inc. recommends changing the default password.

Enabling Customization

To enable customization, click the box to check it. When customization is enabled, the Central Data Station will check the Customization Profile for the location each time an analyzer is downloaded. If the location has the **Enable Updates** option checked, the Central Data Station will update the analyzer with the current Customization Profile for that location as noted below.

- Analyzers designated to Report location as download location in the Instrument workspace will be updated with the Customization Profile assigned to the download location, regardless of the location to which the instrument is assigned. Care should be taken when downloading instruments from locations other then their assigned location.

- Analyzers designated to Always report location as this assignment in the Instrument workspace will always be updated with the Customization Profile for the instrument's assigned location, regardless of the physical location from which it downloads.

If a location has the **Enable Updates** option unchecked, downloading from that location will result in no customization changes being made to analyzers designated to **Report location as download location.** Analyzers designated to **Always report location as this assignment** will not be updated if the assignment location for the instrument has the **Enable Updates** option unchecked, regardless of the setting associated with the physical location from which it downloads.

User can also disable/enable CLEW updates by location. The default setting is to have the CLEW updates occur automatically for all locations. To disable a particular location, simply click on the corresponding check box under **Update CLEW** to remove the check mark.

Default Customization Profile

The first step in customization is to create a default customization profile. This is the profile initially assigned to every new location. To change the default profile, use the directions under Making Selections or click the menu option **Profile ⇨ Change Default** and the item to be changed. The changes in the default profile are automatically applied to every location using the default profile.
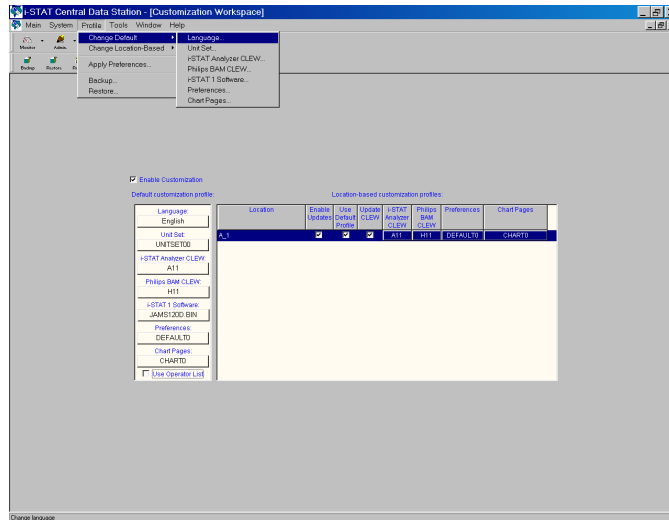
Location-based Customization Profiles

Different customization profiles can be created for different locations. Uncheck the **Use Default Profile** box for the location and double click **i-STAT Analyzer CLEW** or **BAM CLEW** to change the CLEW or double click **Preferences** to change any of the preferences. Alternately, select the menu option **Profile ⇨ Change Location-Based** and the item to be changed. Changes in the customization profile can be made for several locations at once by selecting the locations and then selecting the appropriate option from the Profile Menu. If a location has the **Use Default Profile** option checked, its customization settings will not be changed even if it is selected. Note that Language and the Unit Set from the default customization profile are always used.
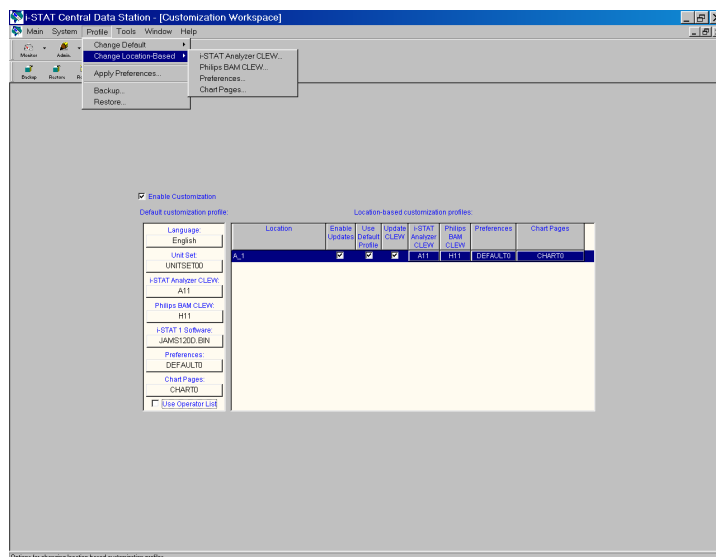
Preferences for locations can also be changed by selecting an existing preference from the Apply Preferences submenu. Select the location or locations to be changed. Click **Profile ➪ Apply Preferences.** Select the desired preferences and click **Apply**. Click **View Preferences** to review a set of preferences.
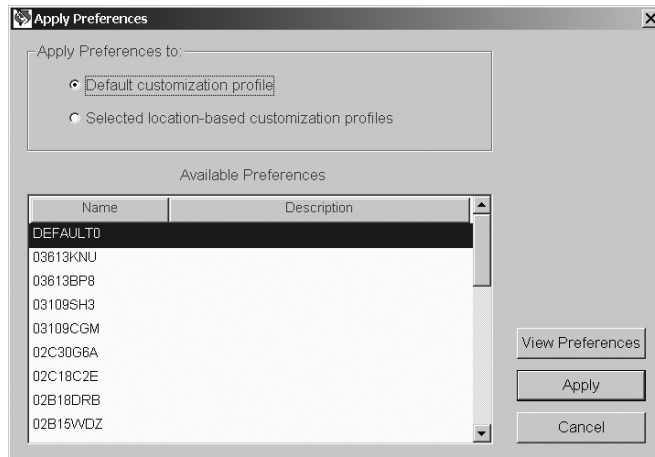
Making Selections   Selections are made from options in the following ways:

- Select one of the seven main Customization options by double clicking the box for **Language**, **Unit Set**, **i-STAT Analyzer CLEW, Philips BAM CLEW, i-STAT 1 Software, Preferences, or Chart Pages**.

- After making a selection in the Language, Unit Set and CLEW window, click the **OK** button to save the selection or click the **Cancel** button to return to the previous selection.

Language Window

Note: Russian is available only on the i-STAT Portable Clinical Analyzer and Portuguese, Danish, and Finnish are available only on the i-STAT 1 Analyzer.

Unit Set Window

Details of each unit set are displayed under the Analytes column. Details are also listed in the Customization section in this manual.
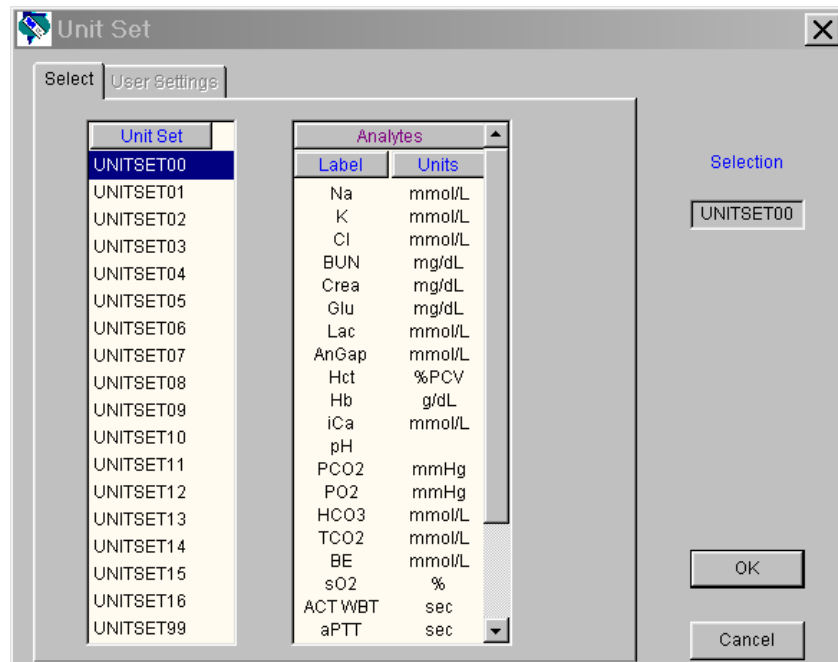
To create a unique unit set, click **UNITSET99** and then the **User Settings** tab. Then select the name and units for each analyte or test.
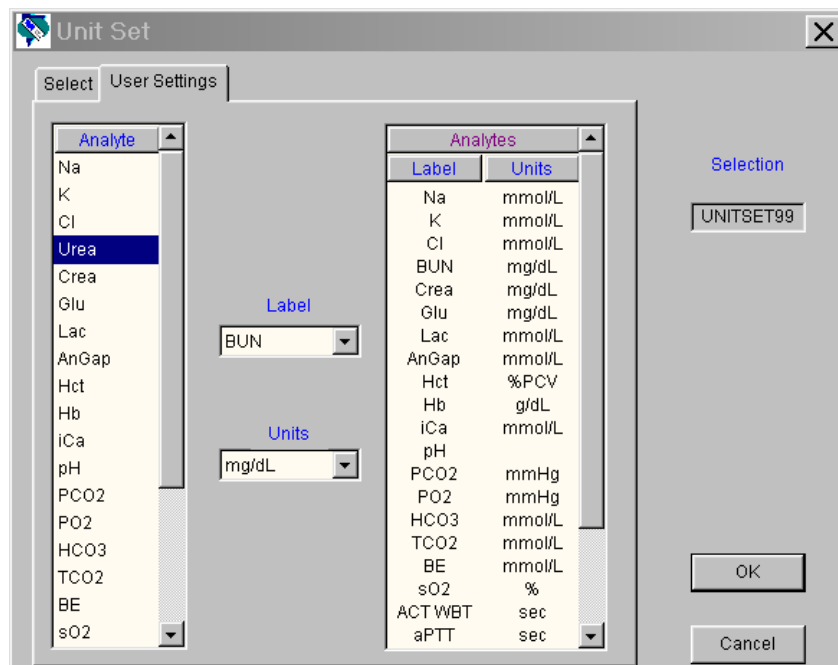
i-STAT Analyzer and Philips BAM CLEW Windows
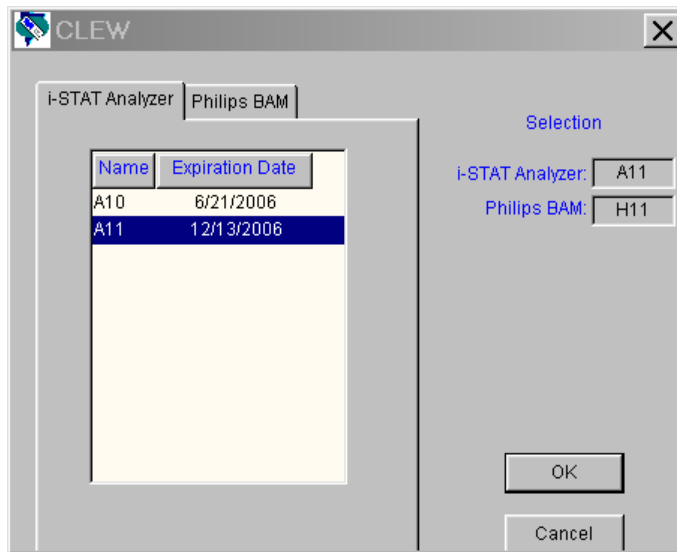
A new CLEW is added to the window via the software update process twice a year. If the **Update CLEWs** feature is active, the Default customization profile must be updated after each new CLEW is added. Click the new CLEW and click OK. Note that there are separate CLEWs for the i-STAT analyzer and the Philips Blood Analysis Module.

Note: Before changing to a new CLEW ensure that all analyzers have been updated to a compatible application software version.

i-STAT 1 Software Window

A new JAMS application software is added to the window via the software update process twice a year. Click the new JAMS and click OK. Selecting the new JAMS aloows users the option of updating their i-STAT 1 analyzers remotely or locally using the Customization Workspace. Please see the Technical Bulletin "Updating Analyzer Software" for full details on performing this procedure. Checking "Disable Software Updates" disables this feature.
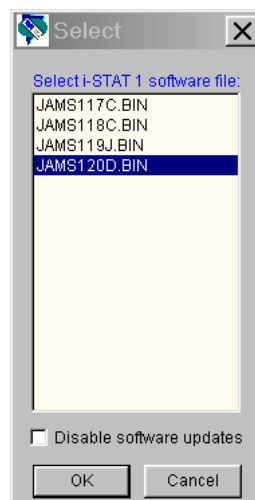
Preferences Window
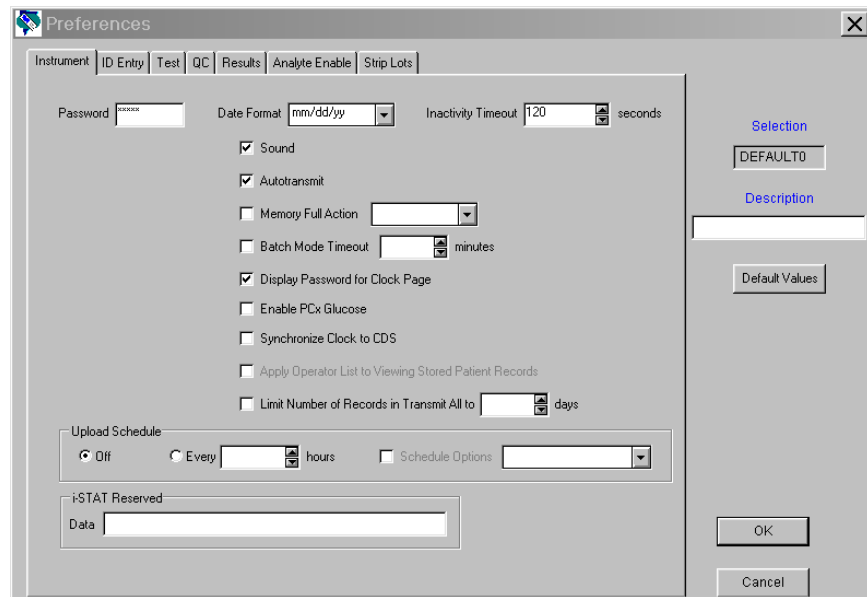
For detailed descriptions of the preferences, see section 9, Customization. The Preferences Window has seven tab pages. Click the tab to display the desired page. The following conventions are used in the Preferences pages:

- Enable/disable an option by clicking the check box to check/uncheck it.

- Change a numeric setting by clicking and holding the ▲ or ▼ symbol or manually entering the number.

- Select an option from a list by clicking the ▼, and selecting the option from the list.

- Select from multiple options by clicking the radio button next to the desired option.

- Enter values into fields, such as for Reference Ranges and Strip Lot Numbers.

When all information has been entered, a button is pressed:

- **Default Values** will restore the default settings to the open window.

- **OK** will store the new settings.

- **Cancel** will ignore any new settings and restore the current settings.

Each Customization Profile is assigned a unique name by the CDS program. This name appears under the Preferences column in the Customization Workspace window, on the Customization screen on the i-STAT 1 Analyzer, on the Analyzer Status screen on the i-STAT Portable Clinical Analyzer and on the Blood Analysis Setup screen of the Blood Analysis Module.

A description can be associated with a profile using the **Description** field in the Preferences Window.

Caution: Close the Customization Workspace when finished to prevent inadvertent changes.

Art: 714384-00F Rev. Date: 16-Apr-15

Chart Page Selection Box

The Chart Page selection box is part of a feature allowing users to customize the Chart Page on their i-STAT 1 analyzers in order to capture user-defined information such as ventillator settings. See the "i-STAT 1 Analyzer Chart Page Customization" Technical Bulletin for full details.

Backup and Restore Profile

The current customization profile can be stored by selecting **Profile** ⇨ **Backup…** from the menu bar or by clicking the **Backup** toolbar button, selecting the directory where the profile is to be stored, typing in a file name for the profile, and clicking the **Save** button.
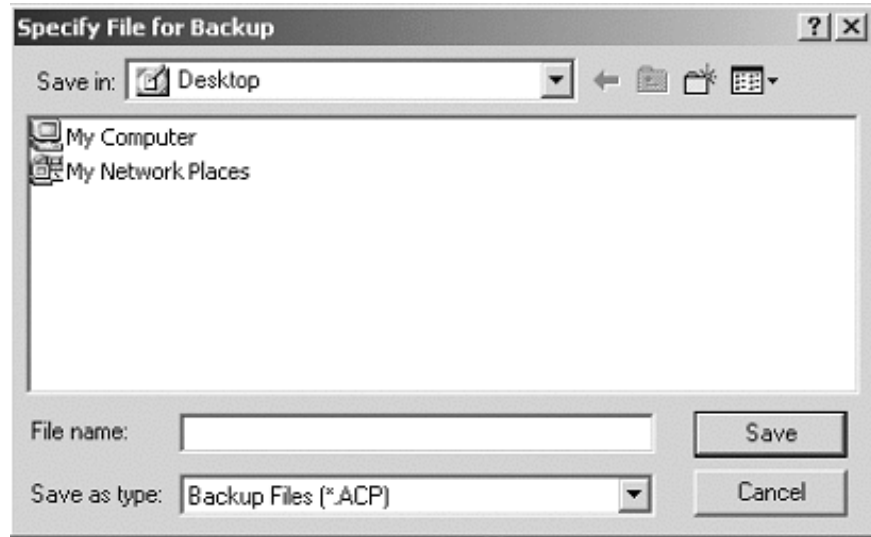
To restore a profile to the CDS, click **Profile** ⇨ **Restore…** or the **Restore** toolbar button. Select the directory and backup file to restore and click the **Open** button.
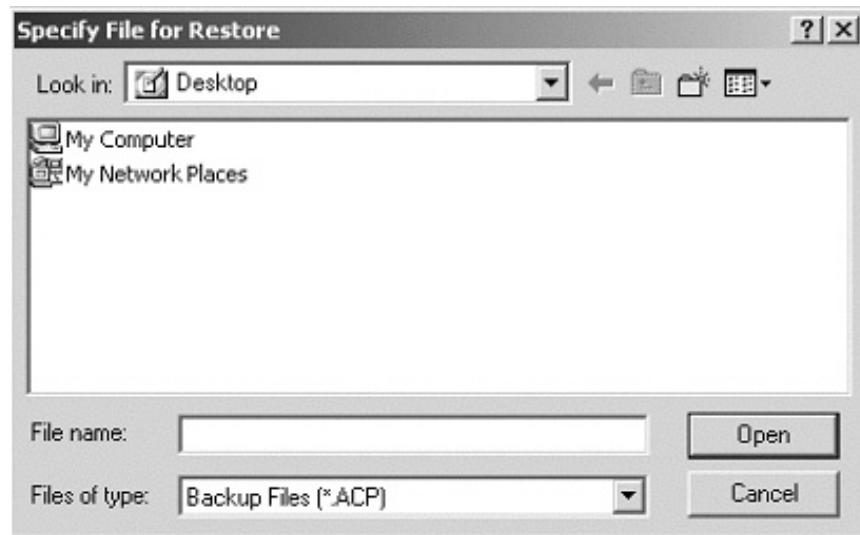
USER ADMINISTRATION WORKSPACE

Overview   The User Administration Workspace is designed as a tool for system administrators. It allows administrators to manage security profiles (a set of security settings determining the access to different CDS screens and functions), manage users, and assign users to security profiles.

Access   Only users designated as administrators can access the User Administration Workspace in the CDS by clicking on **Main ⇨ Open Administration Function ⇨ User Administration**. A Password dialog will then appear. Type in your CDS log-in password and click on **OK**.
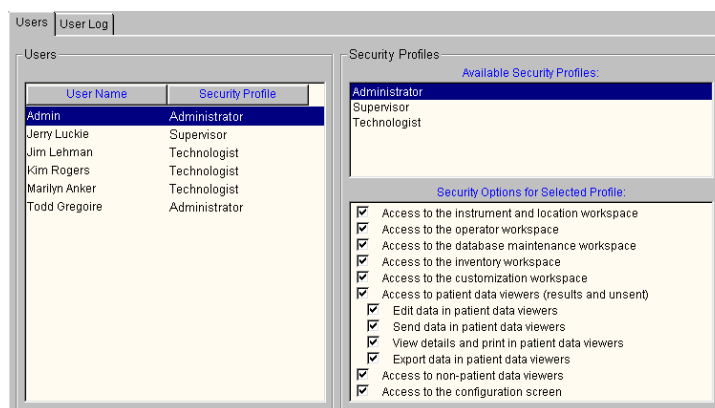
Creating Security Profiles   Once the User Administration Workspace is activated, the Administrator will need to determine how many different security profiles are needed for their facility, and what workspaces and functions should be available to users at those different security levels. Once those decisions have been made, the next step is to create the desired security profiles in the User Administration Workspace.

Please note that an Administrator profile will always exist in the User Administration Workspace. It cannot be edited or deleted, and allows access for those designated users to all CDS Workspaces and functions.

To create a new security profile: click on **Profile ⇨ Add...** An "Add Security Profile" dialog will then appear.
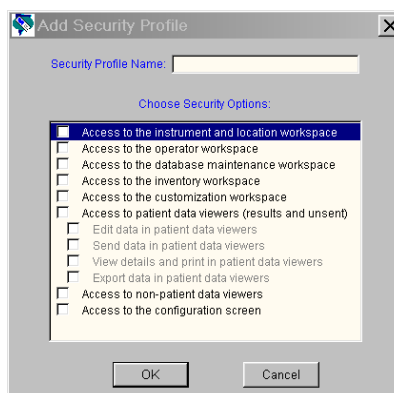
Type in the name of the new Security Profile, then check off the different workspaces and functions users assigned to that security level will be allowed to access, and then click **OK**. The newly created security profile will then be added to the Available Security Profile list.

Deleting Security Profiles

To delete an existing Security Profile, click on the profile you want to delete in the Available Security Profiles window. Click on **Profile ⇨ Delete**, and answer **"Yes"** to the confirmation message that appears on the screen.

Please note that a Security Profile can only be deleted if all of the Users assigned to that particular profile have first been deleted from the Users window. If all of the users have not first been deleted, "Error Accessing Database" and "Error Deleting Profile" messages will appear.

The Administrator Security Profile is permanent and cannot be deleted.

Editing Security Profiles

To edit an existing Security Profile, click on the profile you want to edit in the Available Security Profiles window. Click on **Profile ⇨ Edit**. The name of the profile will then be highlighted in blue. If you wish to edit the profile name, simply type in the new profile name. Then select or deselect the desired listings under the "Security Options for Selected Profile" window by clicking on the corresponding check box.

When all edits are complete, simply click on **Profile ⇨ Edit**, and answer **Yes** to the confirmation message that appears about saving the new changes.

Adding Users

Once all the Security Profiles have been created, the next step is to create users and assign them to the various security profile levels.

To add a user to a security profile when in the User Administration Workspace, click on **User ⇨ Add...**. An Add User box will then appear on the screen.
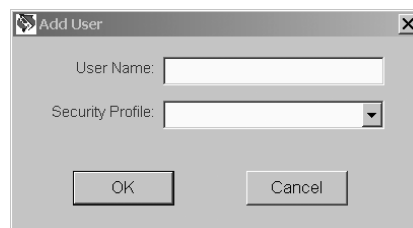
Type in the User Name in the first line, then choose the appropriate Security Profile from the drop down list and click **OK**. The new user listing will then appear in the User window.

Deleting a User
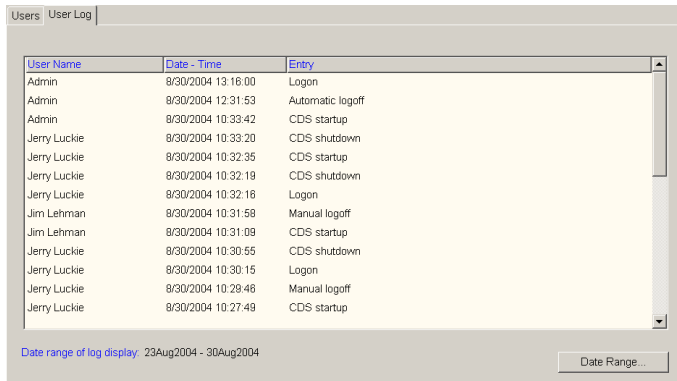
To delete a user, select the user to be deleted, click on **User ⇨ Delete**, and answer **Yes** to the confirmation message. Note: the user who is currently logged on cannot be deleted.

Assigning a User to a Different Profile

To assign an existing user to a different Security Profile, click on **User ⇨ Assign Profile**. A drop down menu will appear next to the user's name. Simply click on the desired Security Profile, then click on **User ⇨ Assign Profile**, and answer **Yes** to the confirmation message that appears asking if you want to save changes.

User Log

The User Log tracks the following user activities: CDS Startup and Shutdown, User Logon, Manual and Automatic User Logoff, and Disabling of the Security feature via the Customization Screen.

User Name	Date - Time	Entry
Admin	8/30/2004 13:16:00	Logon
Admin	8/30/2004 12:31:53	Automatic logoff
Admin	8/30/2004 10:33:42	CDS startup
Jerry Luckie	8/30/2004 10:33:20	CDS shutdown
Jerry Luckie	8/30/2004 10:32:35	CDS startup
Jerry Luckie	8/30/2004 10:32:19	CDS shutdown
Jerry Luckie	8/30/2004 10:32:16	Logon
Jim Lehman	8/30/2004 10:31:58	Manual logoff
Jim Lehman	8/30/2004 10:31:09	CDS startup
Jerry Luckie	8/30/2004 10:30:55	CDS shutdown
Jerry Luckie	8/30/2004 10:30:15	Logon
Jerry Luckie	8/30/2004 10:29:48	Manual logoff
Jerry Luckie	8/30/2004 10:27:49	CDS startup

Date range of log display: 23Aug2004 - 30Aug2004   Date Range...

PASSWORD MANAGEMENT

Passwords

Once all the Security Profiles are created, and all CDS users are assigned to the appropriate Profiles, the Administrator should provide the users with their assigned User Names. Their initial password is **istat**.

When a user logs on to the CDS application for the first time, a dialog box asking for a User Name and Password will appear. They should input their assigned User Name supplied by the Administrator, and the password **istat**. A dialog will then appear indicating that they must change their password. After clicking on **OK**, the following dialog will appear:

Change Password

Old Password: *****

New Password:

New Password Verification: OK

Remember Your Password   Cancel

The user should type in a unique password of their choosing in the space provided, then retype that same password on the New Password Verification line and click **OK**. The password must have a minimum length of 3 alphanumeric characters, and a maximum length of 12 alphanumeric characters.

Once the password is changed, the user will then use their new password for all subsequent CDS log-ons.

Emergency Passwords

If a user forgets their User Name or Password, they have two options for accessing the CDS application:

1. If available, the Administrator can log onto the User Administration Workspace and look up the User Name from the User Window. An Emergency Password for this particular user can then be obtained by performing the following:

a. Click and highlight this particular user's listing in the User Window.

b. Click on **User** ➪ **Emergency Password**. A box will appear with an Emergency Password that this particular user can use. Note: Once this user uses the Emergency Password to log in, they will be immediately prompted to change their password for future CDS log-ins. They cannot continue to use the Emergency Password for log-in purposes.

```
Emergency Password                          [X]

   User Name:    Jim Lehman

    Password:    ZO47299CJ9

                    [  Close  ]
```
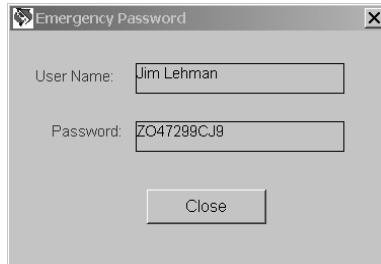
2. If the Administrator is not available, the user can contact their local Support Representative for an emergency User Name and/or password. As with option 1 above, once this user uses the Emergency Password to log in, they will be immediately prompted to change their password for future CDS log-ins. They cannot continue to use the Emergency Password for log-in purposes.

Changing a Password

If a user is logged on to the CDS application, they can choose to change their password at any time by clicking on **Tools** ➪ **Change Password**. A dialog box will appear asking them to enter their Old Password, as well as their New Password (twice). After entering this information, the user clicks on **OK** and answers Yes to the question that appears asking if they really want to change password.

SYSTEM LOGOFFS

Overview

The CDS provides the capability for manual and automatic user logoffs. In the logged off state, the majority of CDS screens and functions are not available. However, analyzer and BAM data can continue to be transmitted to the application, and subsequently sent to the LIS/HIS (if applicable). Also, the monitors remain open if they were open prior to logoff.

Manual Logoff

Once a user has completed their CDS tasks, they can log off by clicking on **System** ➪ **Log Off**. A box will then appear on the screen indicating that the current user has logged off.

```
   The current user is logged off. Press OK to log on.

                    [  OK  ]
```
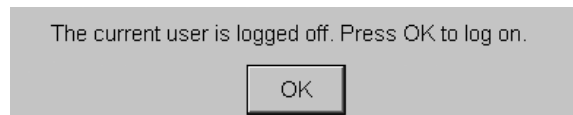
Automatic Logoff

Automatic logoffs are optional and can be enabled in the i-STAT CDS Customization screen, as described in the Security section above on page 22-13.

DATA VIEWERS

Overview

Data from instruments downloaded to the CDS are viewed in the Data Viewers.

Data downloaded from the i-STAT 1 Analyzers can be viewed in separate Data Viewers for Results, QC Codes, Simulator, Unsent Results, Control Results, Calibration Verification (or Linearity) Results and Proficiency Results (external quality control).

Control, Calibration Verification and Proficiency Results from the Portable Clinical Analyzers and Blood Analysis Modules will appear in the Results Data Viewer.
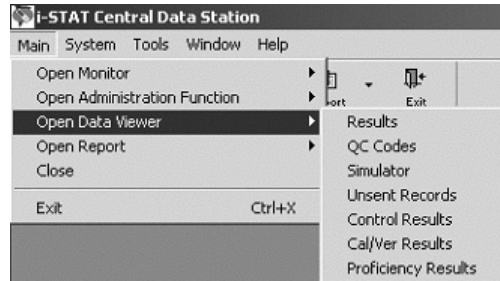
Data from the Medisense Precision PC*x* Plus Glucose Test Strips can now be viewed in the Data Viewers, alongside the data from the Precision PC*x* strip. To determine which strip type was used on a particular testing run, look at the column entitled **Panel**. Precision PC*x* Plus strip runs will be labeled **PCx Plus Glucose**, while Precision PC*x* strip runs will be labeled **PCx Glucose**.

Information in Data Viewers

Data for only one method at a time, such as the i-STAT cartridges, is displayed in a viewer. To switch to a different method, select the method from the selection list in the lower left corner of the viewer. The exception is the Unsent Results Data Viewer which displays results from all methods. Records are listed based on which column is being sorted. Data can be displayed in ascending or descending order by clicking a column as described above.

Example: Results Data Viewer

Refreshing the Data

Data is received continuously by the CDS. Updating the viewers with the continuous incoming stream of data would make viewing the data difficult. Therefore, new data is not added to a viewer until the **Refresh** button is pressed. The window can also be refreshed by pressing **F5** or selecting **Refresh** from the **Window** option menu on the menu bar. The date and time of the latest refresh are listed on the bottom right of the window.

Viewing Details

The details of records in the Results, Control, Cal/Ver, Proficiency and Unsent Results Viewers can be viewed by double clicking the record, by selecting the record and clicking the **Details** toolbar button, or by selecting **Record ⇨ View Details…** from the Menu.

Many of the Extra Data details may be helpful to the Customer Support representative in troubleshooting.

Example of Details for Results Viewer

Customizing the Data Viewers

The viewers can be customized for individual preferences. The following aspects of the viewers are user configurable.

❑ **Selecting a Date Range**

The initial default date range for data in a viewer is the current date and back 7 days. The initial default range can be changed by selecting **Tools ⇨ Customize Viewer ⇨ Date Range…** from the text menu, or by clicking the arrow next to the **Customize** toolbar button, then the **Date Range** button. A default date range can be set but overridden by entering a different date range for display. The maximum default date range allowed is 999 days.

The selection of a shorter date range enhances the system performance by limiting the amount of information needing to be presented. It is always possible to expand the range to view results from earlier and then reset to a more limited default period. The date range function only limits what is presented, not what is in the database.

❑ **Selecting Columns to View**

Columns can be hidden. Select **Tools ⇨ Customize Viewer ⇨ Display Columns** or click the arrow next to the **Customize** toolbar button, then the **Columns** button. To hide a column, click the box following the column's name to uncheck it and then click **OK**. To make the column visible again, click the empty box following the column's name to check it and click the **OK** button.
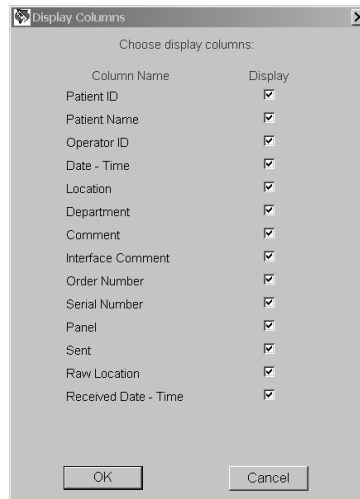
The Raw Location and the Receive Date/Time columns allow users to track the location where particular analyzers are being downloaded, plus the time intervals in which users are transmitting data to the Central Data Station.

❑ **Sorting Data**

For customers who want to sort data in the Data Viewers by multiple column criteria, a new multilevel sorting feature has been added. To access this feature, open the desired Data Viewer, click on **Tools ⇨ Customize Viewer ⇨ Sort**..., or click the arrow next to the **Customize** toolbar button, then the **Sort** button.
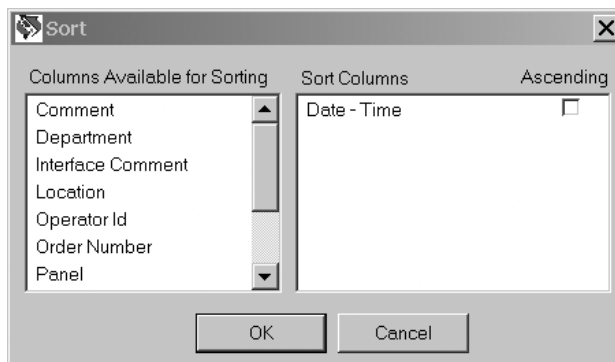
A two-sided Sort dialog will then appear, listing **Columns Available for Sorting** on the left, and **Sort Columns** on the right. Simply click the listing under **Columns Available for Sorting** that you wish to sort your data by, and then drag that column title to the right hand side of the screen under the **Sort Columns section**. Once all of the columns you wish to sort by are under the **Sort Columns** section, check whether you want that particular column to be sorted by ascending or descending order, by placing or removing the check mark in the **Ascending** box.

Once all selections have been made, simply click on **OK** and the sort process will be completed, taking you back to the Data Viewer screen.

Note: By default, the Date/Time column is automatically placed under the **Sort Columns** section with descending order selected. If you do not wish to sort by Date/Time, simply click on that column listing and drag it back to the left side of the screen under **Columns Available For Sorting**.

Editing a Record

To edit a record, highlight the record to be edited, click **Record ⇨ Edit Record** in the menu bar or click the **Edit** toolbar button.

Different viewers have different editable items. Results that have been successfully sent to the LIS or HIS have only an editable Comment. Results marked as **Pending** or **In Progress** cannot be edited.

The Patient ID, Patient Name, Operator ID, Comment, Interface Comment and Order Number can be edited in the Results Viewer. Use the **Tab** key or the mouse to move across the line. The original Patient and Operator IDs will appear along with the edited IDs in the Details window.

Finding a Record

Different viewers have different lists from which to select for a search based on the data presented. Click **Record ⇨ Find...** on the menu bar or click the **Find** toolbar button. Selecting **Sort before finding** before clicking **OK** will present the records in ascending order for the value after the first record matching the search is found.

Type on the Value line the desired parameter then highlight that parameter and click **OK** to find.
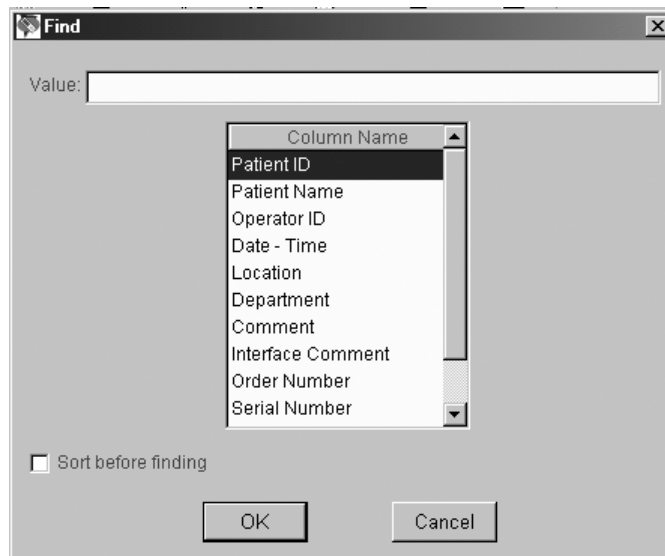
Printing Selected Records

With a Data Viewer open, highlight the records to be printed, click **Record ⇨ Print Selected Records** or click the **Print** toolbar button.

Send Selected Records

With a Data Viewer open, highlight the records to be sent, click **Record ⇨ Send Selected Records** or click the **Send** toolbar button.

Trending Results

Results records in the Results, Control Results, Cal/Ver Results, Proficiency Results and Unsent Results Viewers can be selected for Trend reports. Trends can be performed on Patient ID, Control Lot Number, Calibration Verification Kit Number, Proficiency ID, Operator ID, Analyzer Serial Number or by a selection of records.

With the Data Viewer open, click **Record ⇨ Trend,** then the trend option from the menu bar or click the arrow beside the **Trend** toolbar button and click the desired trend option. Up to 25 records are presented from oldest to newest data.

To trend by selection, highlight the records to be included in the trend report then perform the Trend function.

Example of a Result Trend by Serial Number

QC Codes Viewer

All Quality Check Codes are listed in chronological order. To add a comment, click the record, then **Record ⇨ Edit Record** on the menu bar or click the **Edit Record** toolbar button. To sort the Quality Check Codes by type, click the Quality Code column header. To list again in chronological order, click the Date-Time column header.

Note: Panel is a binary code for the cartridge types.

Electronic Simulator Viewer

All Electronic Simulator results, both external and internal, are listed in chronological order with the newest result at the top of the screen. To view all simulator results together for each analyzer, click the **Serial Number** column header to sort the analyzers by serial number or use the **Find...** option and sort for one analyzer. To list in chronological order again, click the **Date-Time** header.

Location	Date - Time	Serial Number	Comment	Sent	Operator ID	Result		Uses	Simulator Temperature	Pressure	Battery Voltage	Software	Simulator ID ▲
ED	1/12/2001 8:47:00	25351		No	123456	FAIL	L	1255	21.7C	758	8.05V	37C A68	26390
PICU	1/12/2001 8:13:13	300098		No	654987	PASS		977	24.5C	764.1 mm	7.77V	103G-A68	30199
CVOR	1/12/2001 7:44:00	300004		No	123456	PASS		124	23.1C	764.0 mm	8.05V	103G-A68	30201
NICU	1/12/2001 7:41:32	300007		No	456789	PASS		134		764.1 mm	8.05V	103G-A68	30184

To view the actual readings taken during the Electronic Simulator check, click **Record** ⇨ **View Extended Simulator Report...** Note that the **Simulator ID** and **Probe Delta** columns can be viewed in the screen above by scrolling to the right.

Extended Simulator Report

Simulator ID	Probe Delta	Panel	Pot0P	Pot0N	Pot0Z	Pot1P	Pot1N	Pot1Z	Pot2P	Pot2I ▲
INTERNAL		0F	+349.657	-349.692	+0.475	+349.566	-349.681	+0.207	+349.508	-349.72
30144	-0.01C	0F	+250.032	-250.007	-0.007	+250.035	-250.04	-0.018	+250.022	-250.05
30199	+0.00C	0F	+249.932	-249.928	0.00	+249.935	-249.913	+0.042	+249.94	-249.92
30201	+0.00C	0F	+250.00	-249.987	-0.003	+250.011	-249.998	+0.015	+250.001	-249.99
INTERNAL		0F	+349.975	-349.919	+0.572	+349.655	-349.875	+0.295	+349.709	-349.86

Unsent Records Viewer

This viewer is available only if an external interface installed by i-STAT is enabled in the Central Data Station Customization function. This data viewer displays records that have not been sent from the Central Data Station to an external computer system, such as an LIS. The incorrect information can be corrected using **Edit** and the corrected record resent.

Unsent results can be removed from the viewer by highlighting the record, clicking on **Record** ⇨ **Mark Selected Records as Sent,** or by pressing the **F8** Key.

Sent Column Values

Sent Column Value	Definition	Can the record be resent?
No	This is the initial value when a data record is entered into the database.	Yes
Pending	This value means that the record is in the queue waiting to be processed by the Interface.	No
In Progress	This value means that the record is currently being processed by the Interface.	No
Forwarded (HL7 Protocol Only)	This indicates that the Record has been forwarded to the receiving system but has not yet received the Application acknowledgement indicating whether or not the LIS successfully processed the record.	Yes
Yes	This value means that the i-STAT Interface application successfully processed the record. For Data File Protocol Only: • "Yes means that the Data File was successfully created in the c:\istat32\send directory. It does not necessarily mean that the record was processed by the LIS. • It is up to the receiving system to provide a status update to the CDS (See INTER32-SPC-011.doc)	No
Unsuccessful	This value means that the record send was not successful. The Interface Comment will provide some limited information as to why the record send was unsuccessful.	Yes

A data export option is available in the following areas of the Central Data Station application:

    a.   Data Viewers

    b.   Reports

    c.   Trend report, and

    d.   the Extended Simulator report screen

To access this option from any of the Data Viewers or Reports, click on **Window ⇨ Export**. From a Trend report or the Extended Simulator report screen, click on the **Export data…** button at the bottom of the report. A dialog box will then appear on the screen. Choose the file destination location and the type of file you want the exported data saved as from the drop-down menus, then type in the File Name and click on Save.
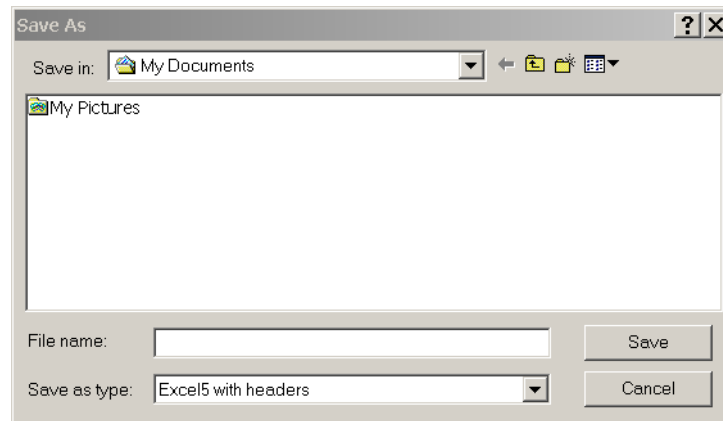
Note: Users can be blocked from or allowed access to this data export feature through the User Administration Workspace by using the check box **"Export data in patient data viewers"** under the **Security Options for Selected Profile** section.
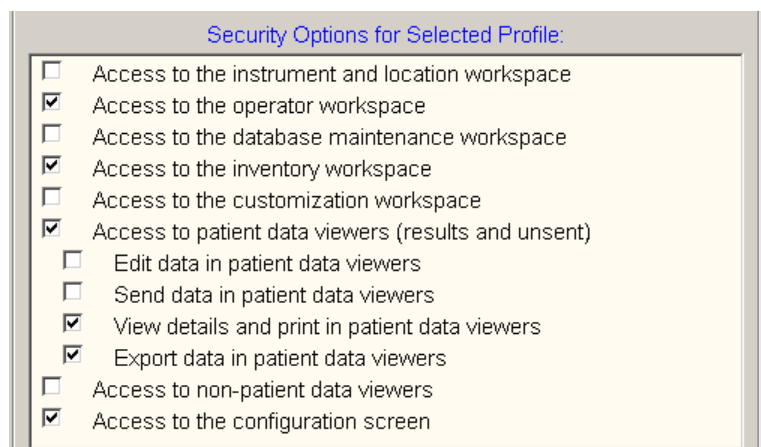
Download Monitor The download monitor quickly identifies the download status of all locations and any locations that have instruments out of download compliance.

The upper portion of the monitor shows the last time an analyzer from the listed locations was downloaded. These columns can be sorted by clicking the column heading.

The maximum time allowed between downloads from the instrument to the CDS is defined under **Download Criteria** in the Instrument/Location workspace. The download status of each location is recorded in the Download Monitor. The **Requires Download** column indicates how many of the total number of analyzers reporting to a location have exceeded the **Download Criteria**. Clicking the location will open the Instrument and Location workspace where noncompliant analyzers will be highlighted.

The monitors are updated or refreshed according to the schedule selected during the customization of the CDS. The data can be manually refreshed by clicking the **Refresh** toolbar button or by pressing the **F5** key.

Most recent downloads:

Location	Method	Most Recent Download
1-ANTHES	i-STAT	14Apr2003 07:29
1-CVOR	i-STAT	12Jun2003 17:13
1-MPACU	i-STAT	14Apr2003 08:27
1-POCT	i-STAT	14Apr2003 14:09
1-STICU 1	i-STAT	14Apr2003 14:28
1-STICU 2	i-STAT	14Apr2003 09:21
1E-PACU	i-STAT	08Apr2003 15:04
1E-PREOP	i-STAT	14Apr2003 11:45

Location	Method	Requires Download
1-ANTHES	i-STAT	2/2
1-CVOR	i-STAT	4/4
1-MPACU	i-STAT	1/1
1-POCT	i-STAT	25/25
1-STICU 1	i-STAT	3/3

Monitor last updated: 11Mar2004 15:58

Interface Monitor

The Interface Monitor accessed via the menu bar functions with an interface installed by Abbott Point of Care Inc. To access the the interface monitor for an interface installed by a third party, click on the **Interface Manager** button in the tray at the bottom of the screen.

The Interface Monitor identifies quickly the status of the Interface to an external computer. The number of pending results is shown as well as any exceptions in the last 72 hours. Clicking an exception takes you to the Unsent Results viewer to address the exception.
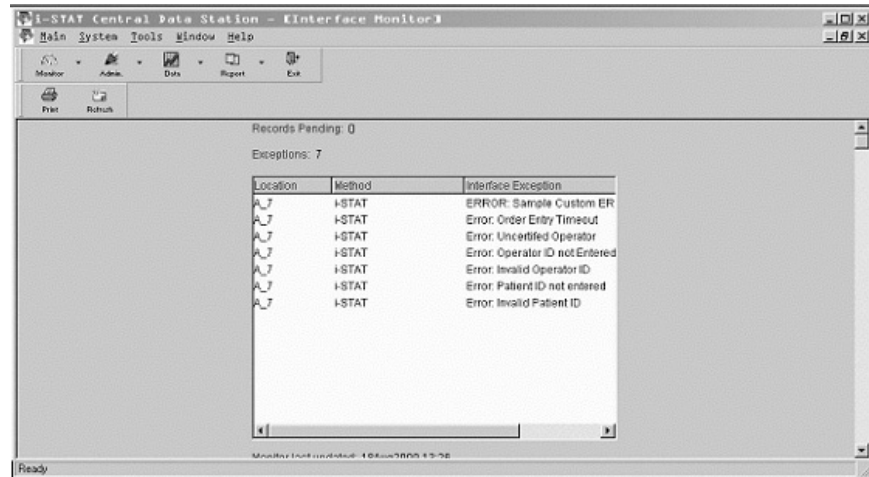
Overview

Reports for managing the point-of-care testing process are available from the CDS program. Three reports can be generated: Reagent Management, Method Competency and Method Compliance. These show information summarized by operator, location, department, or analyzer. Reports can be printed.

Reagent Management

This is a report of cartridge usage by Department or Location. Select a date range for the report. Data in reports, with the exception of "Operator", can be sorted by clicking on the column headers. By Operator data is pre-sorted by department. Select a report by **Reagent Usage by Department, Reagent Usage by Location**, **Reagent Usage by Operator,** or **Reagent Usage by Analyzer,** and then select either **All Locations** or **All Departments**, or select one **Location** or one **Department** from the drop down menu. Select the desired result types (Test, Control, Car/Ver, Proficiency) and then click the **OK** button.

Reagent Usage by Location Report
Method: i-STAT   Result Types: Test Result
Site Name: i-STAT Corporation
Report Covers Dates: 1/1/2002 - 6/13/2003   Location: <Multiple>

Location	Total Cartridges	Total Results	Total Quality Check	Quality Code % of Total	E3+	CG8+	G	6+	G3+	EG7+	Cre
1-ANTHES	469	446	23	4.90%	1	0	0	0	0	445	
1-CVOR	2737	2667	70	2.56%	0	0	1231	1	0	1087	
1E-PACU	24	19	5	20.83%	8	0	2	3	0	6	
1-STICU 1	1825	1783	42	2.30%	4	0	1	1	1675	102	
2E PEDS	131	122	9	6.87%	71	0	12	14	2	7	
3N-NEONATAL	543	483	60	11.05%	134	0	300	8	4	17	
3P-E-RESP	36	36	0	0.00%	0	0	0	0	29	7	
5E ORTHO	112	111	1	0.89%	0	0	0	0	107	3	
6NE CCU1	1416	1374	42	2.97%	4	0	1	10	1282	73	
8N-NICU	1019	996	23	2.26%	19	0	24	5	905	43	
Totals	**8312**	**8037**	**275**	**3.31%**	**241**	**0**	**1571**	**42**	**4004**	**1790**	

Method Compliance

This is a report of exceptions of policy and procedure for cartridge testing by Department, Location or Operator.   This information is available when there is an interface to an external computer.

Select a date range for the report. Select a **Report by Department**, **Location,** or **Operator**, then select **All Locations** or **All Departments** or select one **Location** or **Department** from the list. Click on **Display operator names** if desired. When **Method Compliance by Operator** is selected, operators will be listed by department. Select the filtering criteria for the report and then click the **OK** button.

Method Compliance by Location Report
Method: i-STAT
Site Name: Central Hospital
Report Covers Dates: 9/3/2000 - 10/3/2000   Location: All

Location	Total Records	Total Exceptions	Exceptions % of Total Records	Exception				
				Blank Operator ID	Blank Patient ID	Expired Certifi-cation	Invalid Operator ID	Invalid Patient ID
ACCU	603	29	4.81%	1	0	15	6	7
Cath LAB	12	1	8.33%	0	0	1	0	0
OR	94	5	5.32%	0	0	3	2	0
NICU	13	0	0.00%	0	0	0	0	0
ICU	96	3	3.13%	0	0	3	0	0
Totals	818	38	4.65%	1	0	22	8	7

Method Competence

This is a report of Quality Check Code occurrence for cartridges by Department, Operator, Location or Analyzer.

Select a date range for the report. Select a **Report by Department**, **Location, Operator**, or **Analyzer** and then select **All Locations** or **All Departments** or select one or more **Locations** or **Departments** from the list. Click on **Display operator names** if desired. Select the filtering criteria for the report. Then click the **OK** button.

When **Quality Check Codes by Department** is selected, operators will be listed by Department.

A legend mapping individual code numbers to their respective quality check code categories is available for viewing. To access this legend:

1. Create the desired Quality Check Code report.

2. With the report still on the screen, click on **Report ⇨ View QC Codes by Category...** The following dialog will appear for viewing or printing.

For details of these Quality Check Codes, see the Technical Bulletin: Analyzer Coded Messages.

Customization: Central Data Station Settings	Configuration of the CDS can be viewed.
Customization: i-STAT Analyzer Settings	Customization profiles of the i-STAT analyzers can be viewed.
AutoSend	When enabled, data will be transmitted automatically from the CDS to the LIS or other information management system when received by the CDS. If AutoSend is not enabled, results can be sent to the LIS manually. Highlight the records to be sent in the appropriate Data Viewer Results viewer then click **Record ⇨ Send Selected Records**. If AutoSend is enabled, it will be checkmarked under the System option on the menu bar. If an external interface is not enabled, AutoSend will appear in grey typeface.
Print Option	A Printer Dialog box has been added so that when Print is selected from the menu, the user can choose from a list of installed printers. This allows the user the option to utilize their own network printer. To access this feature, you must perform one of the following:

      a.   Click on **Main ⇨ Print**, or

      b.   Click on **Records ⇨ Print Selected Records**
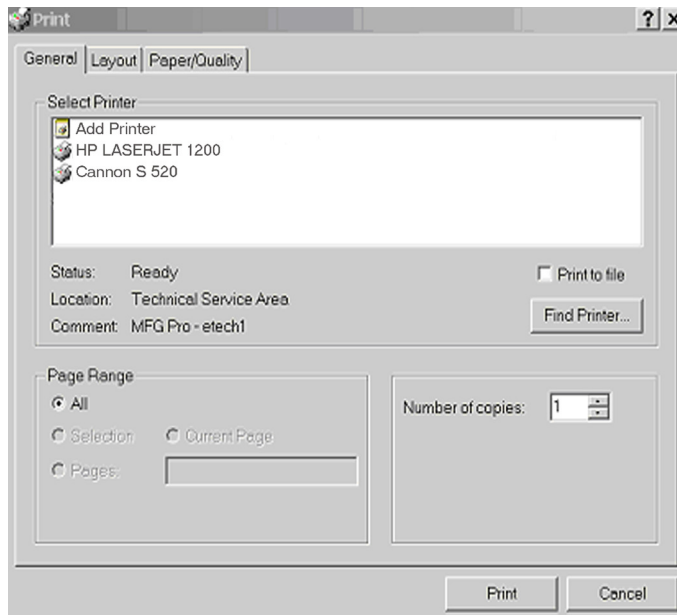
HELP

Technical Support   Phone number for your Customer Support Representative.

About...   Software version of the Central Data Station.

WINDOWS OPERATING SYSTEM AND LANGUAGE SUPPORT

Windows Version/ Service Pack	Windows Language	Supported CDS Language(s)
NT 4.0, SP6a	English	English
2000 Professional, SP4	English	English, German, Italian, Spanish, Swedish
2000 Professional, SP4	German	German, English
2000 Professional, SP4	Italian	Italian, English
2000 Professional, SP4	Spanish	Spanish, English
2000 Professional, SP4	Swedish	Swedish, English
XP Professional, SP2	English	English, German, Italian, Spanish, Swedish
XP Professional, SP2	German	German, English
XP Professional, SP2	Italian	Italian, English
XP Professional, SP2	Spanish	Spanish, English
XP Professional, SP2	Swedish	Swedish, English

During the initial installation or upgrade of the CDS 5 software, all U.S. customers should choose "English" when the language choice drop down menu appears. Failure to do so will result in the following consequences:

1. If the wrong language was chosen during the initial installation of the Version 5 software, all CDS screens will appear in the language chosen. Contact your i-STAT Support Representative if this has occurred.

2. If the wrong language was chosen during an upgrade of the CDS 5 software, the i-STAT installation instructions will appear in the language chosen, but the CDS screens will remain in English.
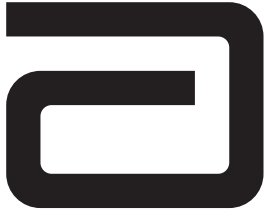
CARTRIDGE AND TEST INFORMATION

i-STAT® sensors are available in a variety of panel configurations. Sensors are contained in cartridges with microfluidic components and, in some cartridges, calibration solution. i-STAT cartridges are used with the i-STAT 1 Analyzer* for the simultaneous quantitative determination of specific analytes and coagulation parameters in whole blood.

CARTRIDGE SPECIFICATIONS

Shelf Life:
Refrigerated at 2 to 8 ºC (35 to 46 ºF) until expiration date.

Refer to the cartridge box for room temperature storage requirements.

Preparation for Use:
Individual cartridges may be used after standing five minutes at room temperature. An entire box of cartridges should stand at room temperature for one hour.

All cartridges should be used immediately after opening pouch. If the pouch has been punctured, the cartridge should not be used.

Sample Type:
Fresh whole blood from arterial, venous, or skin punctures.

(Note: Skin puncture is NOT a recommended sample type for ACT, cTnI, CK-MB, ß-hCG or BNP testing.)

cTnI and CK-MB cartridges require the use of heparinized whole blood or plasma, or non-heparinized whole blood tested within one minute of patient draw.

ß-hCG cartrdiges require the use of heparinized whole blood or plasma samples.

BNP cartridges require the use of EDTA whole blood or plasma samples.

Sample Volume:
17 μL, 20 μL, 40 μL, 65 μL, or 95 μL depending on cartridge type.

Test Timing:
Immediately after collection
- Samples for the measurement of ACT, PT/INR and Lactate

Within 3 minutes after collection
- Samples collected in capillary tubes with balanced heparin anticoagulant
- Samples collected in evacuated or non-evacuated tubes and syringes without anticoagulant

Within 10 minutes after collection
- Samples collected with anticoagulant for the measurement of pH, $P\mathrm{CO}_2$, $P\mathrm{O}_2$, $T\mathrm{CO}_2$ and iCa. Maintain anaerobic conditions. Remix before filling cartridge.

Within 30 minutes after collection
- Samples collected with anticoagulant for the measure of sodium, potassium, chloride, glucose, BUN/urea, creatinine, hematocrit, troponin I, CK-MB, ß-hCG and BNP. Remix thoroughly before testing.

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* The cTnI, CK-MB, ß-hCG and BNP cartridges can only be used with the i-STAT 1 analyzer bearing the [i immuno] symbol.

Analysis Time:
- ACT cartridge: to detection of end point - up to 1000 sec (16.7 min)
- PT/INR cartridge: to detection of end point – up to 300 sec (5 min)
- cTnI, ß-hCG and BNP cartridges: 600 sec (10 min)
- CK-MB cartridge: 300 sec (5 min)
- Other cartridges: typically 130 to 200 sec

Cartridges	Collection Options			
	Syringes	**Evacuated Tubes**	**Capillary Tubes**	**Directly from Skin Puncture**
Cartridges which measure ionized calcium	• Without anticoagulant • With balanced heparin anticoagulant (syringe must be filled to labeled capacity)	• Without anticoagulant • With lithium heparin anticoagulant (tubes must be filled to capacity)	• With balanced heparin anticoagulant	• Not recommended • Not recommended for blood gas analysis; arterial specimens are preferred
Cartridges which perform ACT	• Without anticoagulant ONLY • Syringes must be plastic	• Without anticoagulant, clot activators, or serum separators ONLY • Tubes must be plastic • Devices used to transfer sample to cartridge must be plastic	• Not recommended	• Not recommended
Cartridges which perform PT/INR	• Without anticoagulant ONLY • Syringes must be plastic	• Without anticoagulant, clot activators, or serum separators ONLY • Tubes must be plastic • Devices used to transfer sample to cartridge must be plastic	• Not recommended	• Recommended
Cartridges which measure Troponin I or CK-MB	• With sodium or lithium heparin anticoagulant (syringe must be filled to labeled capacity) • Without anticoagulant if tested within one minute of patient draw	• With sodium or lithium heparin anticoagulant (tubes must be filled to capacity) • Without anticoagulant if tested within one minute of patient draw	• Not recommended	• Not recommended

Art: 714258-00P   Rev. Date: 15-Aug-16

Cartridges	Collection Options			
	Syringes	**Evacuated Tubes**	**Capillary Tubes**	**Directly from Skin Puncture**
Cartridges which measure Total ß-hCG	• With sodium or lithium anticoagulant (syringe must be filled to labeled capacity) • Syringes must be plastic	• With sodium or lithium heparin anticoagulant (tubes must be filled to capacity)	• Not recommended	• Not recommended
Cartridges which measure BNP	• With EDTA anticoagulant (syringe must be filled to labeled capacity) • Syringes must be plastic	• With EDTA anticoagulant (syringe must be filled to labeled capacity) • Syringes must be plastic	• Not recommended	• Not recommended
All other cartridges	• Without anticoagulant • With lithium or balanced heparin anticoagulant (syringe must be filled to labeled capacity)	• Without anticoagulant • With lithium heparin anticoagulant (tubes must be filled to capacity)	• With balanced heparin anticoagulant • With lithium heparin if labeled for the measurement of electrolytes	• While a sample can be transferred directly from a skin puncture to a cartridge, a capillary tube is preferred • Not recommended for blood gas analysis; arterial specimens are preferred

Note Regarding System Reliability

The i-STAT System automatically runs a comprehensive set of quality checks of analyzer and cartridge performance each time a sample is tested. This internal quality system will suppress results if the analyzer or cartridge does not meet certain internal specifications (see Quality Control section in System Manual for detailed information). To minimize the probability of delivering a result with medically significant error the internal specifications are very stringent. It is typical for the system to suppress a very small percentage of results in normal operation given the stringency of these specifications. If however the analyzer or cartridges have been compromised, results may be persistently suppressed, and one or the other must be replaced to restore normal operating conditions. **Where unavailability of results while awaiting replacement of analyzers or cartridges is unacceptable, APOC recommends maintaining both a backup i-STAT System analyzer and cartridges from an alternate lot number.**

EXPECTED VALUES

Measured:

TEST	UNITS	REPORTABLE RANGE	REFERENCE RANGE (arterial)	REFERENCE RANGE (venous)
Sodium/Na	mmol/L (mEq/L)	100 – 180	138 – 146	138 – 146
Potassium/K	mmol/L (mEq/L)	2.0 – 9.0	3.5 – 4.9	3.5 – 4.9
Chloride/Cl	mmol/L (mEq/L)	65 – 140	98 – 109	98 – 109
Glucose/Glu	mmol/L mg/dL g/L	1.1 – 38.9 20 – 700 0.20 – 7.00	3.9 – 5.8 70 – 105 0.70 – 1.05	3.9 – 5.8 70 – 105 0.70 – 1.05
Lactate/Lac	mmol/L mg/dL	0.30 – 20.00 2.7 – 180.2	0.36 – 1.25 3.2 – 11.3	0.90 – 1.70 8.1 – 15.3
Creatinine/Crea	mg/dL µmol/L	0.2 – 20.0 18 – 1768	0.6 – 1.3 53 – 115	0.6 – 1.3 53 – 115
pH		6.5 – 8.2	7.35 – 7.45	7.31 – 7.41
$P\text{CO}_2$	mmHg kPa	5 – 130 0.67 – 17.33	35 – 45 4.67 – 6.00	41 – 51 5.47 – 6.80
TCO$_2$ (on the CHEM8+ cartridge only)	mmol/L (mEq/L)	5 – 50	23 – 27	24 – 29
$P\text{O}_2$	mmHg kPa	5 – 800 0.7 – 106.6	80 – 105 10.7 – 14.0	
Ionized Calcium/iCa	mmol/L mg/dL	0.25 – 2.50 1.0 – 10.0	1.12 – 1.32 4.5 – 5.3	1.12 – 1.32 4.5 – 5.3
Urea Nitrogen/BUN Urea	mg/dL mmol/L mg/dL g/L	3 – 140 1 – 50 6 – 300 0.06 – 3.00	8 – 26 2.9 – 9.4 17 – 56 0.17 – 0.56	8 – 26 2.9 – 9.4 17 – 56 0.17 – 0.56
Hematocrit/Hct	%PCV Fraction	15 – 75 0.15 – 0.75	38 – 51 0.38 – 0.51	38 – 51 0.38 – 0.51
Celite Activated Clotting Time / $^{\text{Celite}}$ACT	seconds	50 – 1000	74 – 125 (Prewarm) 84 – 139 (Nonwarm)	74 – 125 (Prewarm) 84 – 139 (Nonwarm)
The range from 80 - 1000 seconds has been verified through method comparison studies.				
Kaolin Activated Clotting Time / $^{\text{Kaolin}}$ACT	seconds	50 – 1000	74 – 137 (Prewarm) 82 – 152 (Nonwarm)	74 – 137 (Prewarm) 82 – 152 (Nonwarm)
The range from 77 - 1000 seconds has been verified through method comparison studies.				
Prothrombin Time / PT	INR	0.9 – 8.0		
Performance characteristics have not been established for INRs above 6.0.				
Troponin I / cTnI	ng/mL (µg/L)	0.00 – 50.00		0.00 – 0.03* 0.00 – 0.08**
Performance characteristics have not been established for cTnI values above 35.00 ng/mL. ** Represents the 0 to 97.5% range of results.* *** Represents the 0 to 99% range of results.*				
Creatine Kinase MB / CK-MB	ng/mL (µg/L)	0.0 – 150.0		0.0 – 3.5***
***Represents the 0 to 95% range of results.				

EXPECTED VALUES (CONT.)

Measured: (CONT.)

TEST	UNITS	REPORTABLE RANGE	REFERENCE RANGE	
			(arterial)	*(venous)*
B-Type Natriuretic Peptide / BNP	pg/mL (ng/L)	15 – 5000		<15 – 50#
# Represents the 0 to 95% range of results.				
Total Beta-Human Chorionic Gonadotropin /ß-hCG	IU/L	5.0 – 2000.0		<5.0

Calculated:

TEST	UNITS	REPORTABLE RANGE	REFERENCE RANGE	
			(arterial)	*(venous)*
Hemoglobin/Hb	g/dL	5.1 – 25.5	12 – 17	12 – 17
	g/L	51 – 255	120 – 170	120 – 170
	mmol/L	3.2 – 15.8	7 – 11	7 – 11
TCO$_2$ (on all cartridges but the CHEM8+)	mmol/L (mEq/L)	5 – 50	23 – 27	24 – 29
HCO$_3$	mmol/L (mEq/L)	1.0 – 85.0	22 – 26	23 – 28
BE	mmol/L (mEq/L)	(-30) – (+30)	(-2) – (+3)	(-2) – (+3)
Anion Gap/AnGap	mmol/L (mEq/L)	(-10) – (+99)	10 – 20	10 – 20
sO$_2$	%	0 – 100	95 – 98	

CARTRIDGE CONFIGURATIONS AND SAMPLE VOLUME

i-STAT $^{EC}8^+$ (65µL)
Sodium (Na)
Potassium (K)
Chloride (Cl)
pH
PCO_2
Urea Nitrogen (BUN)/Urea
Glucose (Glu)
Hematocrit (Hct)
TCO_2*
HCO_3*
BE*
Anion Gap* (Angap)
Hemoglobin* (Hb)

i-STAT 6^+ (65µL)
Sodium (Na)
Potassium (K)
Chloride (Cl)
Urea Nitrogen (BUN)/Urea
Glucose (Glu)
Hematocrit (Hct)
Hemoglobin* (Hb)

i-STAT $^{EC}4^+$ (65µL)
Sodium (Na)
Potassium (K)
Glucose (Glu)
Hematocrit (Hct)
Hemoglobin* (Hb)

i-STAT $^{E}3^+$ (65µL)
Sodium (Na)
Potassium (K)
Hematocrit (Hct)
Hemoglobin* (Hb)

i-STAT G (65µL)
Glucose (Glu)

i-STAT C_{REA} (65µL)
Creatinine (Crea)

i-STAT $^{EG}7^+$ (95µL)
Sodium (Na)
Potassium (K)
Ionized Calcium (iCa)
Hematocrit (Hct)
pH
PCO_2
PO_2
TCO_2*
HCO_3*
BE*
sO_2*
Hemoglobin* (Hb)

i-STAT $^{EG}6^+$ (95µL)
Sodium (Na)
Potassium (K)
Hematocrit (Hct)
pH
PCO_2
PO_2
TCO_2*
HCO_3*
BE*
sO_2*
Hemoglobin* (Hb)

i-STAT $^{G}3^+$ (95µL)
pH
PCO_2
PO_2
TCO_2*
HCO_3*
BE*
sO_2*

i-STAT $^{CG}4^+$ (95µL)
pH
PCO_2
PO_2
Lactate
TCO_2*
HCO_3*
BE*
sO_2*

i-STAT TOTAL ß-hCG (17µL)
Total Beta-Human Chorionic Gonadotropin

Calculated

i-STAT $^{CG}8^+$ (95µL)
Sodium (Na)
Potassium (K)
Ionized Calcium (iCa)
Glucose (Glu)
Hematocrit (Hct)
pH
PCO_2
PO_2
TCO_2*
HCO_3*
BE*
sO_2*
Hemoglobin* (Hb)

i-STAT $^{Celite}ACT$ (40µL)
Celite® ACT

i-STAT $^{KAOLIN}ACT$ (40µL)
Kaolin ACT

i-STAT PT/INR (20µL)
Prothrombin Time

i-STAT cTnI (17µL)
Troponin I

i-STAT CK-MB (17µL)
Creatine Kinase MB

i-STAT BNP (17µL)
B-type Natriuretic Peptide

i-STAT CHEM8+ (95µL)
Sodium (Na)
Potassium (K)
Chloride (Cl)
Urea Nitrogen (BUN)/Urea
Glucose (Glu)
Creatinine (Crea)
Ionized Calcium (iCa)
TCO_2
Hematocrit (Hct)
Anion Gap* (Angap)
Hemoglobin* (Hb)

Celite is a registered trademark of Celite Corporation, Santa Barbara, CA, for its diatomaceous earth products.

SODIUM/NA

Sodium is measured by ion-selective electrode potentiometry. In the calculation of results for sodium, concentration is related to potential through the Nernst equation.

The i-STAT System uses direct (undiluted) electrochemical methods. Values obtained by direct methods may differ from those obtained by indirect (diluted) methods.[1]

See below for information on factors affecting results. Certain substances, such as drugs, may affect analyte levels *in vivo*.[2]

If results appear inconsistent with the clinical assessment, the patient sample should be retested using another cartridge.

Intended Use

The test for sodium, as part of the i-STAT System, is intended for use in the *in vitro* quantification of sodium in arterial, venous, or capillary whole blood.

Sodium measurements are used for monitoring electrolyte imbalances.

Contents

Each i-STAT cartridge contains one reference electrode (when potentiometric sensors are included in the cartridge configuration), sensors for the measurement of specific analytes and a buffered aqueous calibrant solution that contains known concentrations of analytes and preservatives. For cartridges that contain a sensor for the measurement of sodium, a list of reactive ingredients is indicated below:

Reactive Ingredient	Minimum Quantity
Sodium (Na^+)	121 mmol/L

Metrological Traceability

The i-STAT System test for sodium measures sodium amount-of-substance concentration in the plasma fraction of arterial, venous, or capillary whole blood (dimension mmol L^{-1}) for *in vitro* diagnostic use. Sodium values assigned to i-STAT's controls and calibration verification materials are traceable to the U.S. National Institute of Standards and Technology (NIST) standard reference material SRM956. i-STAT System controls and calibration verification materials are validated for use only with the i-STAT System and assigned values may not be commutable with other methods. Further information regarding metrological traceability is available from Abbott Point of Care Inc.

Expected Values

Test/Abbreviation	Units*	Reportable Range	Reference Range[3]
Sodium/Na	mmol/L (mEq/L)	100–180	138 – 146

*The i-STAT System can be configured with the preferred units.

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The i-STAT reference range for whole blood listed above is similar to reference ranges derived from serum or plasma measurements with standard laboratory methods.

The reference range programmed into the analyzer and shown above is intended to be used as a guide for the interpretation of results. Since reference ranges may vary with demographic factors such as age, gender and heritage, it is recommended that reference ranges be determined for the population being tested.

Clinical Significance

Tests for sodium in the blood are important in the diagnosis and treatment of patients suffering from hypertension, renal failure or impairment, cardiac distress, disorientation, dehydration, nausea and diarrhea. Some causes of increased values for sodium include dehydration, diabetes insipidus, salt poisoning, skin losses, hyperaldosteronism and CNS disorders. Some causes for decreased values for sodium include dilutional hyponatremia (cirrhosis), depletional hyponatremia and syndrome of inappropriate ADH.

Performance Characteristics

The typical performance data summarized below was collected in health care facilities by health care professionals trained in the use of the i-STAT System and comparative methods.

Precision data were collected in multiple sites as follows: Duplicates of each control fluid were tested in the morning and in the afternoon on five days for a total of 20 replicates. The averaged statistics are presented below.

Method comparison data were collected using CLSI guideline EP9-A[4]. Venous blood samples were collected in lithium heparin Vacutainer® tubes and analyzed in duplicate on the i-STAT System. A portion of the specimen was centrifuged and the separated plasma was analyzed in duplicate on comparative methods within 20 minutes of collection.

Deming regression analysis[5] was performed on the first replicate of each sample. In the method comparison table, n is the number of specimens in the data set, Sxx and Syy refer to estimates of imprecision based on the duplicates of the comparative and the i-STAT methods respectively, Sy.x is the standard error of the estimate, and r is the correlation coefficient.*

Method comparisons will vary from site to site due to differences in sample handling, comparative method calibration and other site specific variables.

*The usual warning relating to the use of regression analysis is summarized here as a reminder. For any analyte, "if the data are collected over a narrow range, the estimate of the regression parameters is relatively imprecise and may be biased. Therefore, predictions made from these estimates may be invalid." [4] The correlation coefficient, r, can be used as a guide to assess the adequacy of the comparative method range in overcoming this problem. As a guide, the range of data can be considered adequate for r >0.975.

Precision Data (mmol/L or mEq/L)

Aqueous Control	Mean	SD	%CV
Level 1	120.0	0.46	0.4
Level 3	160.0	0.53	0.3

Method Comparison (mmol/L or mEq/L)

	Beckman Synchron CX®3	Kodak Ektachem™ 700	Nova STAT Profile® 5
n	189	142	192
Sxx	0.74	0.52	0.54
Syy	0.53	0.58	0.53

Slope	1.00	0.98	0.95
Int't	-0.11	3.57	5.26
Sy.x	1.17	1.04	1.53
Xmin	126	120	124
Xmax	148	148	148
r	0.865	0.937	0.838

Cartridge Comparison

The performance characteristics of the sensors are equivalent in all cartridge configurations. System difference analysis was performed on 40 patient samples using the i-STAT 6+ and i-STAT EC4+ cartridges. In the 130–150 mmol/L range the average difference was 0.750.

Factors Affecting Results*

Sodium heparin may increase sodium results up to 1 mmol/L[6].

Hemodilution of the plasma by more than 20% associated with priming cardiopulmonary bypass pumps, plasma volume expansion or other fluid administration therapies using certain solutions may cause clinically significant error on sodium, chloride, ionized calcium and pH results. These errors are associated with solutions that do not match the ionic characteristics of plasma. To minimize these errors when hemodiluting by more than 20%, use physiologically balanced multi-electrolyte solutions containing low-mobility anions (e.g., gluconate).

Interference studies were based on CLSI guideline EP7-A2[7]. Test concentrations used were as per the CLSI guideline unless otherwise indicated.

When added to a plasma pool the following substances (at the concentrations indicated) were found to interfere with the i-STAT sodium assay:

Substance	Test Concentration (mmol/L)	Interference
Bromide	37.5	Use another method. See Note 1 below.
Nithiodote (sodium thiosulfate)	16.7[12]	Increased i-STAT Sodium results. See Note 2 below.

The following substances are known not to significantly interfere with the i-STAT sodium assay at the stated test concentrations:

Substance	Test Concentration (mmol/L)
Acetaminophen	1.32
Acetylcysteine	10.2
Ascorbate	0.34
Bromide *(therapeutic)*	2.5 [8,9,10]
β-Hydroxybutyrate	6.0 [11]
Lactate	6.6
Magnesium Chloride	1.0
Salicylate	4.34

<u>Note</u>:

1) Bromide has been tested at two levels: the CLSI recommended level and a therapeutic plasma concentration level of 2.5 mmol/L. The latter is the peak plasma concentration associated with halothane anesthesia, in which bromide is released. APOC has not identified a therapeutic condition that would lead to levels consistent with the CLSI recommended level. Bromide at a concentration of 37.5 mmol/L increased i-STAT sodium results, while a therapeutic range of bromide (2.5 mmol/L) did not significantly interfere with i-STAT sodium results.

2) Nithiodote (sodium thiosulfate) is indicated for the treatment of acute cyanide poisoning. The journal article titled "Falsely increased chloride and missed anion gap elevation during treatment with sodium thiosulfate" indicated that sodium thiosulfate could be used in the treatment of calciphylaxis indicating that "the highest concentration likely to be seen in plasma [is] after infusion of a 12.5 g dose of sodium thiosulfate pentahydrate. Assuming that the 12.5 g dose of sodium thiosulfate pentahydrate is distributed in a typical blood volume of 5 L with a hematocrit of 40%, the peak sodium thiosulfate plasma concentration expected is 16.7 mmol/L."[12]

*It is possible that other interfering substances may be encountered. The degree of interference at concentrations other than those listed might not be predictable.

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Abbott Park, IL 60064 • USA

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Molenstraat 15
2513 BH, The Hague
The Netherlands

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POTASSIUM/K

Potassium is measured by ion-selective electrode potentiometry. In the calculation of results for potassium, concentration is related to potential through the Nernst equation.

The i-STAT® System uses direct (undiluted) electrochemical methods. Values obtained by direct methods may differ from those obtained by indirect (diluted) methods.[1]

See below for information on factors affecting results. Certain substances, such as drugs, may affect analyte levels *in vivo*.[2]

If results appear inconsistent with the clinical assessment, the patient sample should be retested using another cartridge.

Intended Use

The test for potassium, as part of the i-STAT System, is intended for use in the *in vitro* quantification of potassium in arterial, venous, or capillary whole blood.

Potassium measurements are used in the diagnosis and monitoring of diseases and clinical conditions that manifest high and low potassium levels.

Contents

Each i-STAT cartridge contains one reference electrode (when potentiometric sensors are included in the cartridge configuration), sensors for the measurement of specific analytes and a buffered aqueous calibrant solution that contains known concentrations of analytes and preservatives. For cartridges that contain a sensor for the measurement of potassium, a list of reactive ingredients is indicated below:

Reactive Ingredient	Minimum Quantity
Potassium (K+)	3.6 mmol/L

Metrological Traceability

The i-STAT System test for potassium measures potassium amount-of-substance concentration in the plasma fraction of arterial, venous, or capillary whole blood (dimension mmol L^{-1}) for *in vitro* diagnostic use. Potassium values assigned to i-STAT's controls and calibration verification materials are traceable to the U.S. National Institute of Standards and Technology (NIST) standard reference material SRM956. i-STAT System controls and calibration verification materials are validated for use only with the i-STAT System and assigned values may not be commutable with other methods. Further information regarding metrological traceability is available from Abbott Point of Care Inc.

Expected Values

Test/Abbreviation	Units*	Reportable Range	Reference Range[3]
Potassium/K	mmol/L (mEq/L)	2 – 9	3.5 – 4.9**

*The i-STAT System can be configured with the preferred units.

**The reference range for potassium listed above has been reduced by 0.2 mmol/L from the range cited in Reference 3 to account for the difference between serum and plasma results.

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The i-STAT reference range for whole blood listed above is similar to reference ranges derived from serum or plasma measurements with standard laboratory methods.

The reference range programmed into the analyzer and shown above is intended to be used as a guide for the interpretation of results. Since reference ranges may vary with demographic factors such as age, gender and heritage, it is recommended that reference ranges be determined for the population being tested.

Clinical Significance

Tests for potassium in the blood are important in the diagnosis and treatment of patients suffering from hypertension, renal failure or impairment, cardiac distress, disorientation, dehydration, nausea and diarrhea. Some causes of increased values for potassium include renal glomerular disease, adrenocortical insufficiency, diabetic ketacidosis (DKA), sepsis and *in vitro* hemolysis. Some causes of decreased values for potassium include renal tubular disease, hyperaldosteronism, treatment of DKA, hyperinsulinism, metabolic alkalosis and diuretic therapy.

Performance Characteristics

The typical performance data summarized below was collected in health care facilities by health care professionals trained in the use of the i-STAT System and comparative methods.

Precision data were collected in multiple sites as follows: Duplicates of each control fluid were tested in the morning and in the afternoon on five days for a total of 20 replicates. The averaged statistics are presented below.

Method comparison data were collected using CLSI guideline EP9-A.[4] Venous blood samples were collected in lithium heparin Vacutainer® tubes and analyzed in duplicate on the i-STAT System. A portion of the specimen was centrifuged and the separated plasma was analyzed in duplicate on comparative methods within 20 minutes of collection.

Deming regression analysis[5] was performed on the first replicate of each sample. In the method comparison table, n is the number of specimens in the data set, Sxx and Syy refer to estimates of imprecision based on the duplicates of the comparative and the i-STAT methods respectively, Sy.x is the standard error of the estimate, and r is the correlation coefficient.*

Method comparisons will vary from site to site due to differences in sample handling, comparative method calibration and other site specific variables.

*The usual warning relating to the use of regression analysis is summarized here as a reminder. For any analyte, "if the data are collected over a narrow range, the estimate of the regression parameters is relatively imprecise and may be biased. Therefore, predictions made from these estimates may be invalid."[4] The correlation coefficient, r, can be used as a guide to assess the adequacy of the comparative method range in overcoming this problem. As a guide, the range of data can be considered adequate for r >0.975.

Precision Data (mmol/L or mEq/L)

Aqueous Control	Mean	SD	%CV
Level 1	2.85	0.038	1.3
Level 3	6.30	0.039	0.6

Method Comparison (mmol/L or mEq/L)

	Beckman Synchron CX®3	Kodak Ektachem™ 700	Nova STAT Profile® 5
n	189	142	192
Sxx	0.060	0.031	0.065
Syy	0.055	0.059	0.055
Slope	0.97	1.06	0.99
Int't	0.02	-0.15	-0.01
Sy.x	0.076	0.060	0.112
Xmin	2.8	3.0	2.8
Xmax	5.7	9.2	5.8
r	0.978	0.993	0.948

Cartridge Comparison

The performance characteristics of the sensors are equivalent in all cartridge configurations. System difference analysis was performed on 40 patient samples using the i-STAT 6+ and i-STAT EC4+ cartridges. In the 3.0–5.0 mmol/L range the average difference was 0.049.

Factors Affecting Results*

If heparinized whole blood is allowed to stand before testing, potassium values will first decrease slightly, then increase over time. Potassium values will increase in iced specimens.

Potassium values from anticoagulated samples are preferred to serum values because 0.1 to 0.7 mmol/L potassium can be released from platelets[1] and red blood cells during the clotting process. Potassium values obtained from skin puncture samples may vary due to hemolysis or an increase in tissue fluid from improper technique during the collection procedure.

Interference studies were based on CLSI guideline EP7-A2.[6] Test concentrations used were as per the CLSI guideline unless otherwise indicated.

When added to a plasma pool the following substances (at the concentrations indicated) were found to interfere with the i-STAT potassium assay:

Substance	Test Concentration (mmol/L)	Interference
Bromide	37.5	Use another method. See Note 1 below.
Nithiodote (sodium thiosulfate)	16.7[8]	Decreased i-STAT Potassium results. See Note 2 below.

The following substances are known not to significantly interfere with the i-STAT potassium assay at the stated test concentrations:

Substance	Test Concentration (mmol/L)
Acetaminophen	1.32
Acetylcysteine	10.2
Ascorbate	0.34
Bromide	2.5
ß-Hydroxybutyrate	6.0 [7]
Lactate	6.6
Magnesium Chloride	1.0
Salicylate	4.34

Note 1: Bromide has been tested at two levels: the CLSI recommended level and a therapeutic plasma concentration of 2.5 mmol/L. The latter is the peak plasma concentration associated with halothane

anesthesia, in which bromide is released. APOC has not identified a therapeutic condition that would lead to levels consistent with the CLSI recommended level. Bromide at a concentration of 37.5 mmol/L increased i-STAT potassium results and the rate of potassium star (***) outs, while a therapeutic range of bromide (2.5 mmol/L) did not significantly interfere with i-STAT potassium results.

Note 2: Nithiodote (sodium thiosulfate) is indicated for the treatment of acute cyanide poisoning. The journal article titled "Falsely increased chloride and missed anion gap elevation during treatment with sodium thiosulfate" indicated that sodium thiosulfate could be used in the treatment of calciphylaxis indicating that "the highest concentration likely to be seen in plasma [is] after infusion of a 12.5 g dose of sodium thiosulfate pentahydrate. Assuming that the 12.5 g dose of sodium thiosulfate pentahydrate is distributed in a typical blood volume of 5 L with a hematocrit of 40%, the peak sodium thiosulfate plasma concentration expected is 16.7 mmol/L."[8]

*It is possible that other interfering substances may be encountered. The degree of interference at concentrations other than those listed might not be predictable.

References

1. N.W. Tietz, E.L. Pruden, O. Siggaard-Andersen, "Electrolytes " in Tietz Textbook of Clinical Chemistry—Second Edition, C.A. Burtis and E.R. Ashwood, eds. (Philadelphia: W.B. Saunders Company, 1994).

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2513 BH, The Hague
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CHLORIDE/CL

Chloride is measured by ion-selective electrode potentiometry. In the calculation of results for chloride, concentration is related to potential through the Nernst equation.

The i-STAT System uses direct (undiluted) electrochemical methods. Values obtained by direct methods may differ from those obtained by indirect (diluted) methods.[1]

See below for information on factors affecting results. Certain substances, such as drugs, may affect analyte levels *in vivo*.[2]

If results appear inconsistent with the clinical assessment, the patient sample should be retested using another cartridge.

Intended Use

The test for chloride, as part of the i-STAT System, is intended for use in the *in vitro* quantification of chloride in arterial, venous, or capillary whole blood.

Chloride measurements are primarily used in the diagnosis, monitoring, and treatment of electrolyte and metabolic disorders including, but not limited to, cystic fibrosis, diabetic acidosis, and hydration disorders.

Contents

Each i-STAT cartridge contains one reference electrode (when potentiometric sensors are included in the cartridge configuration), sensors for the measurement of specific analytes and a buffered aqueous calibrant solution that contains known concentrations of analytes and preservatives. For cartridges that contain a sensor for the measurement of chloride, a list of reactive ingredients is indicated below:

Reactive Ingredient	Minimum Quantity
Chloride (Cl⁻)	91 mmol/L

Metrological Traceability

The i-STAT System test for chloride measures chloride amount-of-substance concentration in the plasma fraction of arterial, venous, or capillary whole blood (dimension mmol L^{-1}) for *in vitro* diagnostic use. Chloride values assigned to i-STAT's controls and calibration verification materials are traceable to the U.S. National Institute of Standards and Technology (NIST) standard reference material SRM956. i-STAT System controls and calibration verification materials are validated for use only with the i-STAT System and assigned values may not be commutable with other methods. Further information regarding metrological traceability is available from Abbott Point of Care Inc.

Expected Values

Test/Abbreviation	Units*	Reportable Range	Reference Range[3]
Chloride/CL	mmol/L (mEq/L)	65 – 140	98 – 109

*The i-STAT System can be configured with the preferred units.

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The i-STAT reference range for whole blood listed above is similar to reference ranges derived from serum or plasma measurements with standard laboratory methods.

The reference range programmed into the analyzer and shown above is intended to be used as a guide for the interpretation of results. Since reference ranges may vary with demographic factors such as age, gender and heritage, it is recommended that reference ranges be determined for the population being tested.

Clinical Significance

Tests for chloride in the blood are important in the diagnosis and treatment of patients suffering from hypertension, renal failure or impairment, cardiac distress, disorientation, dehydration, nausea and diarrhea. Some causes of increased values for chloride include prolonged diarrhea, renal tubular disease, hyperparathyroidism and dehydration. Some causes for decreased values for chloride include prolonged vomiting, burns, salt-losing renal disease, overhydration and thiazide therapy.

Performance Characteristics

The performance characteristics of the sensors are equivalent in all cartridge configurations.

The typical performance data summarized below was collected in health care facilities by health care professionals trained in the use of the i-STAT System and comparative methods.

Precision data were collected in multiple sites as follows: Duplicates of each control fluid were tested in the morning and in the afternoon on five days for a total of 20 replicates. The averaged statistics are presented below.

Method comparison data were collected using CLSI guideline EP9-A.[4] Venous blood samples were collected in lithium heparin Vacutainer® tubes and analyzed in duplicate on the i-STAT System. A portion of the specimen was centrifuged and the separated plasma was analyzed in duplicate on comparative methods within 20 minutes of collection.

Deming regression analysis[5] was performed on the first replicate of each sample. In the method comparison table, n is the number of specimens in the data set, Sxx and Syy refer to estimates of imprecision based on the duplicates of the comparative and the i-STAT methods respectively, Sy.x is the standard error of the estimate, and r is the correlation coefficient.*

Method comparisons will vary from site to site due to differences in sample handling, comparative method calibration and other site specific variables.

* The usual warning relating to the use of regression analysis is summarized here as a reminder. For any analyte, "if the data are collected over a narrow range, the estimate of the regression parameters is relatively imprecise and may be biased. Therefore, predictions made from these estimates may be invalid."[4] The correlation coefficient, r, can be used as a guide to assess the adequacy of the comparative method range in overcoming this problem. As a guide, the range of data can be considered adequate for r >0.975.

Precision Data (mmol/L or mEq/L)

Aqueous Control	Mean	SD	%CV
Level 1	76.7	0.54	0.7
Level 3	114.0	0.56	0.5

Method Comparison (mmol/L or mEq/L)

	Beckman Synchron CX®3	Kodak Ektachem 700	Nova STAT Profile® 5
n	189	142	192
Sxx	1.27	0.41	0.89
Syy	0.88	0.90	0.88
Slope	0.99	0.88	0.93
Int't	-0.82	14.6	4.3
Sy.x	1.65	1.84	2.33
Xmin	93	63	96
Xmax	114	128	117
r	0.817	0.914	0.752

Factors Affecting Results*

Hemodilution of the plasma by more than 20% associated with priming cardiopulmonary bypass pumps, plasma volume expansion or other fluid administration therapies using certain solutions may cause clinically significant error on sodium, chloride, ionized calcium and pH results. These errors are associated with solutions that do not match the ionic characteristics of plasma. To minimize these errors when hemodiluting by more than 20%, use physiologically balanced multi-electrolyte solutions containing low-mobility anions (e.g. gluconate).

Interference studies were based on CLSI guideline EP7-A2.[6] Test concentrations used were as per the CLSI guideline unless otherwise indicated.

When added to a plasma pool the following substances (at the concentrations indicated) were found to interfere with the i-STAT chloride assay:

Substance	Test Concentration (mmol/L)	Interference
Acetylcysteine	10.2	Increased i-STAT Chloride results. See Note 1 below.
Bromide	37.5	Use another method. See Note 2 Below.
Bromide (therapeutic)	2.5 [7,8,9]	Increased i-STAT Chloride results. Use another method.
Salicylate	4.34	Increased i-STAT Chloride results. Use another method.
Thiocyanate	6.9	Increased i-STAT Chloride results. Use another method.
Nithiodote (sodium thiosulfate)	16.7[15]	Increased i-STAT Chloride results. See Note 4 below.

The following substances are known not to significantly interfere with the i-STAT chloride assay at the stated test concentrations:

Substance	Test Conc. (mmol/L)
Acetaminophen	1.32
Acetylcysteine (therapeutic)	0.30 [10,11,12]
Ascorbate	0.34
β-Hydroxybutyrate	6.0 [13]
Lactate	6.6
Salicylate (therapeutic)	0.5 [14]

Notes:

1) Acetylcysteine has been tested at two levels: the CLSI recommended level and a concentration of 0.30 mmol/L. The latter is 3 times the peak plasma therapeutic concentration associated with treatment to reverse acetaminophen poisoning. APOC has not identified a therapeutic condition that would lead to levels consistent with the CLSI recommended level. Acetylcysteine at a concentration of 10.2 mmol/L increased i-STAT chloride results, while an acetylcysteine concentration of 0.30 mmol/L did not significantly interfere with i-STAT chloride results.

2) Bromide has been tested at two levels: the CLSI recommended level and a therapeutic plasma concentration level of 2.5 mmol/L. The latter is the peak plasma concentration associated with halothane anesthesia, in which bromide is released. APOC has not identified a therapeutic condition that would lead to levels consistent with the CLSI recommended level. Bromide at a concentration of 37.5 mmol/L and 2.5 mmol/L increased i-STAT chloride results.

3) Salicylate has been shown to interfere at a concentration proscribed by the CLSI guideline, 4.34 mmol/L, which represents a toxic concentration. Salicylate at 0.5 mmol/L, which represents the upper end of the therapeutic concentration, has been shown not to significantly interfere with i-STAT chloride results.

4) Nithiodote (sodium thiosulfate) is indicated for the treatment of acute cyanide poisoning. The journal article titled "Falsely increased chloride and missed anion gap elevation during treatment with sodium thiosulfate" indicated that sodium thiosulfate could be used in the treatment of calciphylaxis indicating that "the highest concentration likely to be seen in plasma [is] after infusion of a 12.5 g dose of sodium thiosulfate pentahydrate. Assuming that the 12.5 g dose of sodium thiosulfate pentahydrate is distributed in a typical blood volume of 5 L with a hematocrit of 40%, the peak sodium thiosulfate plasma concentration expected is 16.7 mmol/L."[15]

*It is possible that other interfering substances may be encountered. The degree of interference at concentrations other than those listed might not be predictable.

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2513 BH, The Hague
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BUN/UREA

Urea is hydrolyzed to ammonium ions in a reaction catalyzed by the enzyme urease.

$$\text{Urea} + H_2O + 2H^+ \xrightarrow{\text{urease}} 2NH_4^+ + CO_2$$

The ammonium ions are measured potentiometrically by an ion-selective electrode. In the calculation of results for urea, concentration is related to potential through the Nernst Equation.

See below for information on factors affecting results. Certain substances, such as drugs, may affect analyte levels *in vivo*.[1]

If results appear inconsistent with the clinical assessment, the patient sample should be retested using another cartridge.

Intended Use

The test for blood urea nitrogen (BUN/urea), as part of the i-STAT® System, is intended for use in the *in vitro* quantification of BUN/urea in arterial, venous, or capillary whole blood.

Blood urea nitrogen measurements are used for the diagnosis, monitoring, and treatment of certain renal and metabolic diseases.

Contents

Each i-STAT cartridge contains one reference electrode (when potentiometric sensors are included in the cartridge configuration), sensors for the measurement of specific analytes, and a buffered aqueous calibrant solution that contains known concentrations of analytes and preservatives. For cartridges that contain a sensor for the measurement of urea nitrogen, a list of reactive ingredients is indicated below:

Reactive Ingredient	Biological Source	Minimum Quantity
Urea	N/A	4 mmol/L
Urease	*Canavalia ensiformis*	0.12 IU

Metrological Traceability

The i-STAT System test for blood urea nitrogen/urea measures blood urea nitrogen/urea amount-of-substance concentration in the plasma fraction of arterial, venous, or capillary whole blood (dimension mmol L^{-1}) for *in vitro* diagnostic use. BUN/urea values assigned to i-STAT's controls and calibration verification materials are traceable to the U.S. National Institute of Standards and Technology (NIST) standard reference material SRM909. i-STAT System controls and calibration verification materials are validated for use only with the i-STAT System and assigned values may not be commutable with other methods. Further information regarding metrological traceability is available from Abbott Point of Care Inc.

Expected Values

Test/Abbreviation	Units*	Reportable Range	Reference Range[2]
Urea Nitrogen/BUN	mg/dL	3 – 140	8 – 26
Urea	mmol/L	1 – 50	2.9 – 9.4
Urea	mg/dL	6 – 300	17 - 56
Urea	g/L	0.06 – 3.00	0.17 - 0.56

*The i-STAT System can be configured with the preferred units.

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To convert a BUN result in mg/dL to a urea result in mmol/L, multiply the BUN result by 0.357. To convert a urea result in mmol/L to a urea result in mg/dL, multiply the mmol/L result by 6. To convert a urea result in mg/dL to a urea result in g/L, divide the mg/dL result by 100.

The i-STAT reference ranges for whole blood listed above are similar to reference ranges derived from serum or plasma measurements with standard laboratory methods.

The reference range programmed into the analyzer and shown above is intended to be used as a guide for the interpretation of results. Since reference ranges may vary with demographic factors such as age, gender and heritage, it is recommended that reference ranges be determined for the population being tested.

Clinical Significance

An abnormally high level of urea nitrogen in the blood is an indication of kidney function impairment or failure. Some other causes of increased values for urea nitrogen include prerenal azotemia (e.g. shock), postrenal azotemia, GI bleeding and a high protein diet. Some causes of decreased values for urea nitrogen include pregnancy, severe liver insufficiency, overhydration and malnutrition.

Performance Characteristics

The typical performance data summarized below were collected in health care facilities by health care professionals trained in the use of the i-STAT System and comparative methods.

Precision data were collected in multiple sites as follows: Duplicates of each control fluid were tested in the morning and in the afternoon on five days for a total of 20 replicates. The averaged statistics are presented below.

Method comparison data were collected using CLSI guideline EP9-A.[3] Venous blood samples were collected in lithium heparin Vacutainer® tubes and analyzed in duplicate on the i-STAT System. A portion of the specimen was centrifuged and the separated plasma was analyzed in duplicate on comparative methods within 20 minutes of collection.

Deming regression analysis[4] was performed on the first replicate of each sample. In the method comparison table, n is the number of specimens in the data set, Sxx and Syy refer to estimates of imprecision based on the duplicates of the comparative and the i-STAT methods, respectively, Sy.x is the standard error of the estimate, and r is the correlation coefficient.*

Method comparisons will vary from site to site due to differences in sample handling, comparative method calibration and other site specific variables.

*The usual warning relating to the use of regression analysis is summarized here as a reminder. For any analyte, "if the data are collected over a narrow range, the estimate of the regression parameters is relatively imprecise and may be biased. Therefore, predictions made from these estimates may be invalid."[4] The correlation coefficient, r, can be used as a guide to assess the adequacy of the comparative method range in overcoming this problem. As a guide, the range of data can be considered adequate for r >0.975.

Precision Data (mg/dL)

Aqueous Control	Mean	SD	%CV
Level 1	52.8	0.76	1.4
Level 3	5.5	0.45	8.2

Method Comparison (mg/dL)

	Beckman Coulter LX20®	Dade Dimension RxL-Xpand®	Beckman Coulter CX9®
n	39	32	26
Sxx	0.36	0.48	0.39
Syy	0.67	0.34	0.60
Slope	1.03	1.05	1.00
Int't	1.39	-0.28	-0.38
Sy.x	0.99	0.31	0.85
Xmin	5	5	7
Xmax	70	38	66
r	0.997	0.998	0.997

Cartridge Comparison

The performance characteristics of the sensors are equivalent in all cartridge configurations. System difference analysis was performed on 40 patient samples using the i-STAT 6+ and i-STAT EC8+ cartridges. In the 25–60 mg/dL range the average difference was -1.13. In the 60–140 mg/dL range the average difference was -0.77.

Factors Affecting Results*

Endogenous ammonium ions will not affect results.

Interference studies were based on CLSI guideline EP7-A2.[5] Test concentrations used were as per the CLSI guideline unless otherwise indicated.

When added to a plasma pool the following substances (at the concentrations indicated) were found to interfere with the i-STAT BUN assay:

Substance	Test Concentration (mmol/L)	Interference
Bromide	37.5	Use another method. See Note 1 below.
Hydroxyurea	0.92	Increased i-STAT BUN/UREA results. See Note 2 below.
Nithiodote (sodium thiosulfate)	16.7[7]	Decreased i-STAT BUN/UREA results. See Note 3 below.

The following substances were shown not to significantly interfere with the i-STAT BUN assay at the stated test concentrations:

Substance	Test Concentration (mmol/L)
Acetaminophen	1.32
Acetylcysteine	10.2
Ascorbate	0.34
Bromide	2.5
β-Hydroxybutyrate	6.0 [6]
Lactate	6.6
Salicylate	4.34

Thiocyanate	6.9

Notes:

1) Bromide has been tested at two levels: the CLSI recommended level and a therapeutic plasma concentration of 2.5 mmol/L. The latter is the peak plasma concentration associated with halothane anesthesia, in which bromide is released. APOC has not identified a therapeutic condition that would lead to levels consistent with the CLSI recommended level. Bromide at a concentration of 37.5 mmol/L decreased i-STAT BUN/UREA results and increased the rate of BUN/UREA star (***) outs, while a therapeutic range of bromide (2.5 mmol/L) did not significantly interfere with i-STAT BUN/UREA results.

2) Hydroxyurea is a DNA synthesis inhibitor used in the treatment of various forms of cancer, sickle cell anemia, and HIV infection. This drug is used to treat malignancies including melanoma, metastatic ovarian cancer, and chronic myelogenous leukemia. It is also used in the treatment of polycythemia vera, thrombocythemia, and psoriasis. At typical doses ranging from 500 mg to 2 g/day, concentrations of hydroxyurea in patients' blood may be sustained at approximately 100 to 500 µmol/L. Higher concentrations may be observed soon after dosing or at higher therapeutic doses.

3) Nithiodote (sodium thiosulfate) is indicated for the treatment of acute cyanide poisoning. The journal article titled "Falsely increased chloride and missed anion gap elevation during treatment with sodium thiosulfate" indicated that sodium thiosulfate could be used in the treatment of calciphylaxis indicating that "the highest concentration likely to be seen in plasma [is] after infusion of a 12.5 g dose of sodium thiosulfate pentahydrate. Assuming that the 12.5 g dose of sodium thiosulfate pentahydrate is distributed in a typical blood volume of 5 L with a hematocrit of 40%, the peak sodium thiosulfate plasma concentration expected is 16.7 mmol/L."[7]

*It is possible that other interfering substances may be encountered. The degree of interference at concentrations other than those listed might not be predictable.

References

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100 and 200 Abbott Park Road
Abbott Park, IL 60064 • USA

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Emergo Europe
Molenstraat 15
2513 BH, The Hague
The Netherlands

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GLUCOSE/GLU

Glucose is measured amperometrically. Oxidation of glucose, catalyzed by the enzyme glucose oxidase, produces hydrogen peroxide (H_2O_2). The liberated hydrogen peroxide is oxidized at the electrode to produce a current which is proportional to the sample glucose concentration.
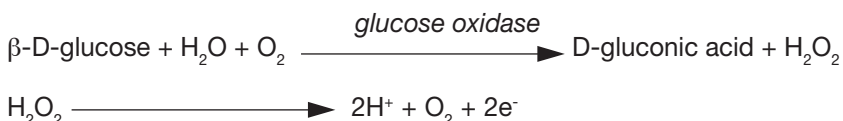
$$\beta\text{-D-glucose} + H_2O + O_2 \xrightarrow{\quad glucose\ oxidase \quad} \text{D-gluconic acid} + H_2O_2$$

$$H_2O_2 \xrightarrow{\qquad\qquad} 2H^+ + O_2 + 2e^-$$

See below for information on factors affecting results. Certain substances, such as drugs, may affect analyte levels *in vivo*.[1]

If results appear inconsistent with the clinical assessment, the patient sample should be retested using another cartridge.

Intended Use

The test for glucose, as part of the i-STAT® System, is intended for use in the *in vitro* quantification of glucose in arterial, venous, or capillary whole blood.

Glucose measurements are used in the diagnosis, monitoring, and treatment of carbohydrate metabolism disorders including, but not limited to, diabetes mellitus, neonatal hypoglycemia, idiopathic hypoglycemia, and pancreatic islet cell carcinoma.

Contents

Each i-STAT cartridge contains one reference electrode (when potentiometric sensors are included in the cartridge configuration), sensors for the measurement of specific analytes, and a buffered aqueous calibrant solution that contains known concentrations of analytes and preservatives. For cartridges that contain a sensor for the measurement of glucose, a list of reactive ingredients is indicated below:

Reactive Ingredient	Biological Source	Minimum Quantity
Glucose	N/A	7 mmol/L
Glucose Oxidase	*Aspergillus niger*	0.002 IU

Metrological Traceability

The i-STAT System test for glucose measures glucose amount-of-substance concentration in the plasma fraction of arterial, venous, or capillary whole blood (dimension mmol L^{-1}) for *in vitro* diagnostic use. Glucose values assigned to i-STAT's controls and calibration verification materials are traceable to the U.S. National Institute of Standards and Technology (NIST) standard reference material SRM965. i-STAT System controls and calibration verification materials are validated for use only with the i-STAT System and assigned values may not be commutable with other methods. Further information regarding metrological traceability is available from Abbott Point of Care Inc.

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Expected Values

Test/Abbreviation	Units*	Reportable Range	Reference Range[2]
Glucose/Glu	mg/dL	20 – 700	70 – 105
(fasting)	mmol/L	1.1 – 38.9	3.9 – 5.8
	g/L	0.20 – 7.00	0.70 – 1.05

* The i-STAT System can be configured with the preferred units.

To convert a result from mg/dL to mmol/L, multiply the mg/dL value by 0.055.

The i-STAT reference ranges for whole blood listed above are similar to reference ranges derived from serum or plasma measurements with standard laboratory methods.

The reference range programmed into the analyzer and shown above is intended to be used as a guide for the interpretation of results. Since reference ranges may vary with demographic factors such as age, gender and heritage, it is recommended that reference ranges be determined for the population being tested.

Clinical Significance

Glucose is a primary energy source for the body and the only source of nutrients for brain tissue. Measurements for determination of blood glucose levels are important in the diagnosis and treatment of patients suffering from diabetes and hypoglycemia. Some causes for increased values of glucose include diabetes mellitus, pancreatitis, endocrine disorders (e.g., Cushing's syndrome), drugs (e.g., steroids, thyrotoxicosis), chronic renal failure, stress, or I.V. glucose infusion. Some causes of decreased values of glucose include insulinoma, adrenocortical insufficiency, hypopituitarism, massive liver disease, ethanol ingestion, reactive hypoglycemia, and glycogen storage disease.

Performance Characteristics

The typical performance data summarized below was collected in health care facilities by health care professionals trained in the use of the i-STAT System and comparative methods.

Precision data were collected at multiple sites as follows: Duplicates of each control fluid were tested in the morning and in the afternoon on five days for a total of 20 replicates. The averaged statistics are presented below.

Method comparison data were collected using CLSI guideline EP9-A.[3] Venous blood samples were collected in lithium heparin Vacutainer® tubes and analyzed in duplicate on the i-STAT System. A portion of the specimen was centrifuged and the separated plasma was analyzed in duplicate on comparative methods within 20 minutes of collection.

Deming regression analysis[4] was performed on the first replicate of each sample. In the method comparison table, n is the number of specimens in the data set, Sxx and Syy refer to estimates of imprecision based on the duplicates of the comparative and the i-STAT methods respectively, Sy.x is the standard error of the estimate, and r is the correlation coefficient.*

Method comparisons will vary from site to site due to differences in sample handling, comparative method calibration and other site specific variables.

* The usual warning relating to the use of regression analysis is summarized here as a reminder. For any analyte, "if the data are collected over a narrow range, the estimate of the regression parameters is relatively imprecise and may be biased. Therefore, predictions made from these estimates may be invalid."[4] The correlation coefficient, r, can be used as a guide to assess the adequacy of the comparative method range in overcoming this problem. As a guide, the range of data can be considered adequate for r >0.975.

Precision Data (mg/dL)

Aqueous Control	Mean	SD	%CV
Level 1	41.8	0.68	1.6
Level 3	289	2.4	0.8

Method Comparison (mg/dL)

	Beckman Coulter LX20	Bayer 860	Dade Dimension RxL-Xpand
n	35	40	32
Sxx	2.21	4.71	0.98
Syy	0.69	0.96	0.59
Slope	1.03	0.99	1.01
Int't	-3.39	-1.67	-0.85
Sy.x	0.91	0.70	1.57
Xmin	45	58	48
Xmax	297	167	257
r	0.999	0.993	0.998

Cartridge Comparison

The performance characteristics of the sensors are equivalent in all cartridge configurations. System difference analysis was performed on 34 patient samples using the i-STAT CHEM8+ and i-STAT CG8+ cartridges. In the 65–249 mg/dL range, the average difference was 0.80.

Factors Affecting Results*

Glucose values will decrease in whole blood samples over time. Venous blood glucose is as much as 7 mg/dL less than capillary blood glucose as a result of tissue utilization.[5]

Interference studies were based on CLSI guideline EP7-A2.[6] Test concentrations used were as per the CLSI guideline unless otherwise indicated.

When added to a plasma pool the following substances (at the concentrations indicated) were found to interfere with the i-STAT glucose assay:

Substance	Test Concentration (mmol/L)	Interference
Acetaminophen	1.32	Increased i-STAT Glucose results. See Note 1 Below.
Acetylcysteine	10.2	Decreased i-STAT Glucose results. See Note 2 below.
Bromide	37.5	Use another method. See Note 3 below.
Bromide *(therapeutic)*	2.5 [7,8,9]	Decreased i-STAT Glucose results. See Note 3 below.
Hydroxyurea	0.92	Increased i-STAT Glucose results. Use another method.
Thiocyanate	6.9	Decreased i-STAT Glucose results.
Nithiodote (sodium thiosulfate)	16.7[14]	Decreased i-STAT Glucose results. See Note 7 below.

The following substances are known not to significantly interfere with the i-STAT glucose assay at the stated test concentrations:

Substance	Test Concentration (mmol/L)
Acetaldehyde	0.045 [10]
Acetaminophen *(therapeutic)*	0.132 [10]
Acetoacetate	2.0
Acetylcysteine *(therapeutic)*	0.3 [11,12]
Ascorbate	0.34

Dopamine	0.006
Formaldehyde	0.133 [10]
β–Hydroxybutyrate	6.0 [13]
Lactate	6.6
Maltose	13.3
Pyruvate	0.31
Salicylate	4.34
Thiocyanate (therapeutic)	0.5 [15]
Uric Acid	1.4

<u>Notes</u>:

1) Acetaminophen has been shown to interfere with glucose results in the i-STAT 6+, EC8+, EC4+ and G products, at a concentration prescribed by the CLSI guideline, 1.32 mmol/L, which represents a toxic concentration of acetaminophen. Acetaminophen at 0.132 mmol/L, which represents the upper end of the therapeutic concentration, has been shown not to significantly interfere with i-STAT glucose results for all i-STAT cartridges. Acetaminophen at a test level of 1.32 mmol/L (toxic concentration) has been shown not to significantly interfere with glucose results in the i-STAT CHEM8+ and CG8+ products.

2) Acetylcysteine has been tested at two levels: the CLSI recommended level and a concentration of 0.30 mmol/L. The latter is 3 times the peak plasma therapeutic concentration associated with treatment to reverse acetaminophen poisoning. APOC has not identified a therapeutic condition that would lead to levels consistent with the CLSI recommended level. Acetylcysteine at a concentration of 10.2 mmol/L decreased i-STAT glucose results, while acetylcysteine at a concentration of 0.3 mmol/L did not significantly interfere with i-STAT glucose results.

3) Bromide has been tested at two levels: the CLSI recommended level and a therapeutic plasma concentration level of 2.5 mmol/L. The latter is the peak plasma concentration associated with halothane anesthesia, in which bromide is released. APOC has not identified a therapeutic condition that would lead to levels consistent with the CLSI recommended level. Bromide tested at concentrations of 2.5 and 37.5 mmol/L decreased i-STAT glucose results.

4) Hydroxyurea is a DNA synthesis inhibitor used in the treatment of various forms of cancer, sickle cell anemia, and HIV infection. This drug is used to treat malignancies including melanoma, metastatic ovarian cancer, and chronic myelogenous leukemia. It is also used in the treatment of polycythemia vera, thrombocythemia, and psoriasis. At typical doses ranging from 500 mg to 2 g/day, concentrations of hydroxyurea in patients' blood may be sustained at approximately 100 to 500 µmol/L. Higher concentrations may be observed soon after dosing or at higher therapeutic doses.

5) The dependence of the i-STAT glucose with respect to pH is as follows: Values below 7.4 at 37°C decrease results by approximately 0.9 mg/dL (0.05 mmol/L) per 0.1 pH units. Values above 7.4 at 37°C increase results by approximately 0.8 mg/dL (0.04 mmol/L) per 0.1 pH units.

6) The dependence of the i-STAT glucose with respect to PO_2 is as follows: Oxygen levels of less than 20 mmHg (2.66 kPa) at 37°C may decrease results.

7) Nithiodote (sodium thiosulfate) is indicated for the treatment of acute cyanide poisoning. The journal article titled "Falsely increased chloride and missed anion gap elevation during treatment with sodium thiosulfate" indicated that sodium thiosulfate could be used in the treatment of calciphylaxis indicating that "the highest concentration likely to be seen in plasma [is] after infusion of a 12.5 g dose of sodium thiosulfate pentahydrate. Assuming that the 12.5 g dose of sodium thiosulfate pentahydrate is distributed in a typical blood volume of 5 L with a hematocrit of 40%, the peak sodium thiosulfate plasma concentration expected is 16.7 mmol/L." [14]

* It is possible that other interfering substance may be encountered. The degree of interference at concentrations other than those listed might not be predictable.

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100 and 200 Abbott Park Road
Abbott Park, IL 60064 • USA

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Molenstraat 15
2513 BH, The Hague
The Netherlands

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HEMATOCRIT/HCT AND CALCULATED HEMOGLOBIN/HB

Hematocrit is determined conductometrically. The measured conductivity, after correction for electrolyte concentration, is inversely related to the hematocrit.

See below for information on factors affecting results. Certain substances, such as drugs, may affect analyte levels *in vivo*.[1]

If results appear inconsistent with the clinical assessment, the patient sample should be retested using another cartridge.

Intended Use

The test for hematocrit, as part of the i-STAT® System, is intended for use in the *in vitro* quantification of packed red blood cell volume fraction in arterial, venous, or capillary whole blood.

Hematocrit measurements can aid in the determination and monitoring of normal or abnormal total red cell volume status including, but not limited to, conditions such as anemia, erythrocytosis, and blood loss related to trauma and surgery.

Contents

Each i-STAT cartridge contains one reference electrode (when potentiometric sensors are included in the cartridge configuration), sensors for the measurement of specific analytes, and a buffered aqueous calibrant solution of known conductance that contains known concentrations of analytes and preservatives.

Metrological Traceability

The i-STAT System test for hematocrit measures packed red blood cell volume fraction in arterial, venous, or capillary whole blood (expressed as the % packed cell volume) for *in vitro* diagnostic use. Hematocrit values assigned to i-STAT's working calibrators are traceable to the Clinical and Laboratory Standards Institute (CLSI) H7-A3 procedure for determining packed cell volume by the microhematocrit method.[2] Further information regarding metrological traceability is available from Abbott Point of Care Inc.

Expected Values

Test/Abbreviation	Units*	Reportable Range	Reference Range[3]
Hematocrit/Hct	%PCV	15 – 75	38 – 51**
	Fraction	0.15 – 0.75	0.38 – 0.51
Hemoglobin/Hb	g/dL	5.1 – 25.5	12 – 17
	g/L	51 – 255	120 – 170
	mmol/L	3.2 – 15.8	7 – 11

* The i-STAT System can be configured with the preferred units.

**The reference ranges for hematocrit and hemoglobin span both female and male populations.

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To convert a result from %PCV to fraction packed cell volume, divide the %PCV result by 100. For the measurement of hematocrit, the i-STAT System can be customized to agree with methods calibrated by the microhematocrit reference method using either K_3EDTA or K_2EDTA anticoagulant. Mean cell volumes of K_3EDTA anticoagulated blood are approximately 2-4% less than K_2EDTA anticoagulated blood.[2] While the choice of anticoagulant affects the microhematocrit method to which all hematocrit methods are calibrated, results from routine samples on hematology analyzers are independent of the anticoagulant used. Since most clinical hematology analyzers are calibrated by the microhematocrit method using K_3EDTA anticoagulant, the i-STAT System default customization is K_3EDTA.

The reference range programmed into the analyzer and shown above is intended to be used as a guide for the interpretation of results. Since reference ranges may vary with demographic factors such as age, gender and heritage, it is recommended that reference ranges be determined for the population being tested.

Clinical Significance

Hematocrit is a measurement of the fractional volume of red blood cells. This is a key indicator of the body's state of hydration, anemia or severe blood loss, as well as the blood's ability to transport oxygen. A decreased hematocrit can be due to either overhydration, which increases the plasma volume, or a decrease in the number of red blood cells caused by anemias or blood loss. An increased hematocrit can be due to loss of fluids, such as in dehydration, diuretic therapy, and burns, or an increase in red blood cells, such as in cardiovascular and renal disorders, polycythemia vera, and impaired ventilation.

Performance Characteristics

The typical performance data summarized below were collected in health care facilities by health care professionals trained in the use of the i-STAT System and comparative methods.

Precision data were collected in multiple sites as follows: Duplicates of each control fluid were tested in the morning and in the afternoon on five days for a total of 20 replicates. The averaged statistics are presented below.

Method comparison data were collected using CLSI guideline EP9-A[4]. Venous blood samples, collected in lithium heparin Vacutainer® tubes, were analyzed in duplicate on the i-STAT System and on the comparative methods for hematocrit within 20 minutes of collection.

Deming regression analysis[5] was performed on the first replicate of each sample. In the method comparison table, n is the number of specimens in the data set, Sxx and Syy refer to estimates of imprecision based on the duplicates of the comparative and the i-STAT methods respectively, Sy.x is the standard error of the estimate, and r is the correlation coefficient.*

Method comparisons will vary from site to site due to differences in sample handling, comparative method calibration and other site specific variables.

Interference studies were based on CLSI guideline EP7-P.[6]

*The usual warning relating to the use of regression analysis is summarized here as a reminder: For any analyte, "if the data is collected over a narrow range, the estimate of the regression parameters are relatively imprecise and may be biased. Therefore, predictions made from these estimates may be invalid".[5] The correlation coefficient, r, can be used as a guide to assess the adequacy of the comparative method range in overcoming this problem. As a guide, the range of data can be considered adequate if r>0.975.

Precision Data (%PCV)

Whole Blood Control	Mean	SD	%CV
Low	30.0	0.44	1.5
High	49.0	0.50	1.0

Method Comparison (%PCV)

	Coulter® S Plus	Nova STAT Profile® 5	Abbott Cell-Dyn 4000	Sysmex SE9500
n	142	192	29	29
Sxx	0.50	0.46	0.41	0.53
Syy	1.09	1.31	0.77	0.76
Slope	0.98	1.06	1.06	1.11
Int't	1.78	-3.98	-1.42	-4.19
Sy.x	2.03	2.063	1.13	0.98
Xmin	18	21	19	24
Xmax	51	50	46	47
r	0.952	0.932	0.993	0.980

Factors Affecting Results*

The measurement of certain blood samples with high erythrocyte sedimentation rates (ESR) may be affected by analyzer angle. While testing blood samples, beginning ninety (90) seconds after the cartridge is inserted, the analyzer should remain level until a result is obtained. A level surface includes running the handheld in the downloader/recharger.

Interferent	Effect
WBC	Grossly elevated white blood cell counts may increase results.
Total Protein	Hematocrit results are affected by the level of total protein as follows:

Displayed Result	TP < 6.5 g/dL	TP > 8.0 g/dL
HCT < 40 %PCV	Hct decreased by ~1% PCV for each decrease of 1 g/dL TP	Hct increased by ~1% PCV for each increase 1 g/dL TP
HCT > 40 % PCV	Hct decreased by ~0.75 % PCV for each decrease of 1 g/dL TP	Hct increased by ~0.75 %PCV for each increase 1 g/dL TP

Total protein levels may be low in neonatal and burn patient populations, as well as in additional clinical populations listed in Statland.[3] Total protein levels may also be decreased in patients undergoing cardiopulmonary bypass (CPB) or ECMO, and with patients receiving large volumes of saline-based IV fluids. Care should be taken when using hematocrit results from patients with total protein levels below the adult reference range (6.5 to 8 g/dL).

The CPB sample type can be used to correct the hematocrit result for the dilutional affect of the pump prime in cardiovascular surgery. The CPB algorithm assumes that cells and plasma are diluted equally and that the pump priming solution has no added albumin or other colloid or packed red blood cells. Since perfusion practices vary, it is recommended that each practice verify the use of the CPB sample type and the length of time in which the CPB sample type should be used during the recovery period. Note that for hematocrit values above 30 %PCV, the CPB correction is ≤1.5 %PCV; the size of the correction at this level should not impact transfusion decisions.

Lipids	Abnormally high lipids may increase results. Interference from lipids will be about two-thirds the size of the interference from protein.

Sodium	The sample electrolyte concentration is used to correct the measured conductivity prior to reporting hematocrit results. Factors that affect sodium will therefore also affect hematocrit.
Bromide	Bromide (37.5 mmol/L) is known to result in an increased rate of star (***) outs. Bromide has been tested at two levels: the CLSI recommended level and a therapeutic plasma concentration level of 2.5 mmol/L. The latter is the peak plasma concentration associated with halothane anesthesia, in which bromide is released. APOC has not identified a therapeutic condition that would lead to levels consistent with the CLSI recommended level. Bromide at a concentration of 37.5 mmol/L increased the rate of HCT star (***) outs, while a therapeutic range of bromide (2.5 mmol/L) did not significantly interfere with i-STAT HCT results.

*It is possible that other interfering substances may be encountered. These results are representative and your results may differ somewhat due to test-to-test variation. The degree of interference at concentrations other than those listed might not be predictable.

Sample Collection and Handling

Erroneous hematocrit results can be obtained by improper sample handling.

- Hematocrit results can be affected by the settling of red blood cells in the collection device. The best way to avoid the affect of settling is to test the sample immediately. If there is a delay in testing of a minute or more, the sample must be remixed thoroughly:
  - ❏ If the sample is in a collection tube, invert the tube gently 10 times.
  - ❏ If the sample is in a syringe, roll the syringe between the palms for five seconds in one direction, then roll in a second direction for five seconds, then gently invert repeatedly for five seconds. Note that it may not be possible to adequately mix a blood sample in a 1 mL syringe. Samples from 1 mL syringes should not be used to determine hematocrit if testing is delayed. Discard one or two drops of blood from a syringe before filling a cartridge.

- Low hematocrit results can be caused by contamination of flush solutions in an arterial or venous line.
  - ❏ Back flush a line with a sufficient amount of blood to remove intravenous solutions, heparin or medications that may contaminate the sample. Five to six times the volume of the catheter, connectors and needle is recommended.

Cartridge Comparison

The performance characteristics of the sensors are equivalent in all cartridge configurations. System difference analysis was performed on 40 patient samples using the i-STAT 6+ and i-STAT E3+ cartridges. In the 15–30 %PCV range the average difference was 0.462. In the 30–50 %PCV range the average difference was 0.097.

Calculated Result for Hemoglobin

The i-STAT System provides a calculated hemoglobin result which is determined as follows[7]:

hemoglobin (g/dL) = hematocrit (% PCV) x 0.34

hemoglobin (g/dL) = hematocrit (decimal fraction) x 34

To convert a hemoglobin result from g/dL to mmol/L, multiply the displayed result by 0.621. The calculation of hemoglobin from hematocrit assumes a normal MCHC.

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Abbott Point of Care Inc.
100 and 200 Abbott Park Road
Abbott Park, IL 60064 • USA

EC REP

Emergo Europe
Molenstraat 15
2513 BH, The Hague
The Netherlands

CE

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Art: 714178-00Q

Rev. Date: 15-Aug-16

IONIZED CALCIUM/ICA

Ionized calcium is measured by ion-selective electrode potentiometry. In the calculation of results for ionized calcium concentration is related to potential through the Nernst equation. Results are measured at 37°C.

See below for information on factors affecting results. Certain substances, such as drugs, may affect analyte levels *in vivo*.[1]

If results appear inconsistent with the clinical assessment, the patient sample should be retested using another cartridge.

Intended Use

The test for ionized calcium, as part of the i-STAT® System, is intended for use in the *in vitro* quantification of ionized calcium in arterial, venous, or capillary whole blood.

Ionized calcium measurements are used in the diagnosis, monitoring, and treatment of conditions including, but not limited to, parathyroid disease, a variety of bone diseases, chronic renal disease, tetany, and disturbances related to surgical and intensive care.

Contents

Each i-STAT cartridge contains one reference electrode (when potentiometric sensors are included in the cartridge configuration), sensors for the measurement of specific analytes, and a buffered aqueous calibrant solution that contains known concentrations of analytes and preservatives. For cartridges that contain a sensor for the measurement of ionized calcium, a list of reactive ingredients is indicated below:

Reactive Ingredient	Minimum Quantity
Calcium (Ca^{2+})	0.9 mmol/L

Metrological Traceability

The i-STAT System test for ionized calcium measures ionized calcium (*i.e.* free calcium ion) amount-of-substance concentration in the plasma fraction of arterial, venous, or capillary whole blood (dimension mmol L^{-1}) for *in vitro* diagnostic use. Ionized calcium values assigned to i-STAT's controls and calibration verification materials are traceable to the U.S. National Institute of Standards and Technology (NIST) standard reference material SRM956. i-STAT System controls and calibration verification materials are validated for use only with the i-STAT System and assigned values may not be commutable with other methods. Further information regarding metrological traceability is available from Abbott Point Care Inc.

Expected Values

Test/Abbreviation	Units*	Reportable Range	Reference Range[2]
Ionized Calcium/iCa	mmol/L	0.25 – 2.50	1.12 – 1.32
	mg/dL	1.0 – 10.0	4.5 – 5.3

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To convert a result from mmol/L to mg/dL, multiply the mmol/L value by 4. To convert mmol/L to mEq/L multiply the mmol/L value by 2.

The reference range programmed into the analyzer and shown above is intended to be used as a guide for the interpretation of results. Since reference ranges may vary with demographic factors such as age, gender and heritage, it is recommended that reference ranges be determined for the population being tested.

Clinical Significance

Although most of the calcium in blood is bound to protein or complexed to smaller anionic species, the biologically active fraction of calcium is free ionized calcium. Through its role in a number of enzymatic reactions and in membrane transport mechanisms, ionized calcium is vitally important in blood coagulation, nerve conduction, neuromuscular transmission and in muscle contraction. Increased ionized calcium (hypercalcemia) may result in coma. Other symptoms reflect neuromuscular disturbances, such as hyperreflexia and/or neurologic abnormalities such as neurasthenia, depression or psychosis. Decreased ionized calcium (hypocalcemia) often results in cramps (tetany), reduced cardiac stroke work and depressed left ventricular function. Prolonged hypocalcemia may result in bone demineralization (osteoporosis) which can lead to spontaneous fractures. Measurements of ionized calcium have proven of value under the following clinical conditions: transfusion of citrated blood, liver transplantation, open heart surgery, neonatal hypocalcemia, renal disease, hyperparathyroidism, malignancy, hypertension and pancreatitis.

Performance Characteristics

The typical performance data summarized below was collected in health care facilities by health care professionals trained in the use of the i-STAT System and comparative methods.

Precision data were collected in multiple sites as follows: Duplicates of each control fluid were tested in the morning and in the afternoon on five days for a total of 20 replicates. The averaged statistics are presented below.

Method comparison data were collected using CLSI guideline EP9-A[3]. Venous blood samples were collected in lithium heparin Vacutainer® tubes and analyzed in duplicate on the i-STAT System and on the comparative methods within 10 minutes of each other.

Deming regression analysis[4] was performed on the first replicate of each sample. In the method comparison table, n is the number of specimens in the data set, Sxx and Syy refer to estimates of imprecision based on the duplicates of the comparative and the i-STAT methods respectively, Sy.x is the standard error of the estimate, and r is the correlation coefficient.*

Method comparisons will vary from site to site due to differences in sample handling, comparative method calibration and other site specific variables.

* The usual warning relating to the use of regression analysis is summarized here as a reminder. For any analyte, "if the data are collected over a narrow range, the estimate of the regression parameters is relatively imprecise and may be biased. Therefore, predictions made from these estimates may be invalid."[4] The correlation coefficient, r, can be used as a guide to assess the adequacy of the comparative method range in overcoming this problem. As a guide, the range of data can be considered adequate for r >0.975.

Precision Data (mmol/L)

Aqueous Control	Mean	SD	%CV
Level 1	1.60	0.017	1.1
Level 3	0.84	0.012	1.4

Method Comparison (mmol/L)

	Radiometer ICA1	Nova STAT Profile
n	47	57
Sxx	0.009	0.017
Syy	0.017	0.017
Slope	0.925	0.960
Int't	0.113	0.062
Sy.x	0.035	0.029
Xmin	0.46	0.53
Xmax	2.05	2.05
r	0.982	0.982

Cartridge Comparison

The performance characteristics of the sensors are equivalent in all cartridge configurations. System difference analysis was performed on 24 patient samples using i-STAT CHEM8+ and i-STAT CG8+ cartridges. In the 0.46 - 1.23 mmol/L range, the average difference was 0.003.

Factors Affecting Results*

Venous stasis (prolonged tourniquet application) and forearm exercise may increase ionized calcium due to a decrease in pH caused by localized production of lactic acid[5]. Exposing the sample to air will cause an increase in pH due to the loss of CO_2 which will decrease ionized calcium.

Heparin binds calcium. Each unit of heparin added per mL of blood will decrease ionized calcium by 0.01 mmol/L.[5] Therefore, the correct ratio of heparin anticoagulant to blood must be achieved during sample collection. Intravenous injection of 10,000 units of heparin has been shown in adults to cause a significant decrease of ionized calcium of about 0.03 mmol/L.[5] Use only unheparinized sample transfer devices when using i-STAT's aqueous control and calibration verification materials.

Hemodilution of the plasma by more than 20% associated with priming cardiopulmonary bypass pumps, plasma volume expansion or other fluid administration therapies using certain solutions may cause clinically significant error on sodium, chloride, ionized calcium and pH results. These errors are associated with solutions that do not match the ionic characteristics of plasma. To minimize these errors when hemodiluting by more than 20%, use physiologically balanced multi-electrolyte solutions containing low-mobility anions (e.g., gluconate).

Interference studies were based on CLSI guideline EP7-A2.[6] Test concentrations used were as per the CLSI guideline unless otherwise indicated.

When added to a plasma pool, the following substances (at the concentration indicated) were found to interfere with the i-STAT Ionized Calcium assay:

Substance	Test Concentration (mmol/L)	Interference
Acetaminophen	1.32	Decreased i-STAT Ionized Calcium results. See Note below.
Acetylcysteine	10.2	Decreased i-STAT Ionized Calcium results. See Note below.
Bromide	37.5	Use another method. See Note below.
Magnesium	1.0	Increased i-STAT Ionized Calcium results by up to 0.04 mmol/L.
Lactate	6.6	Decreased i-STAT Ionized Calcium results by up to 0.07 mmol/L.
Nithiodote (sodium thiosulfate)	16.7[14]	Decreased i-STAT Ionized Calcium results. See Note below.
Salicylate	4.34	Decreased i-STAT Ionized Calcium results. See Note below.
Salicylate *(therapeutic)*	0.5 [9]	Decreased i-STAT Ionized Calcium results by up to 0.03 mmol/L. See Note below.
Thiocyanate	6.9	Decreased i-STAT Ionized Calcium results. Use another method.

The following substances are known not to significantly interfere with the i-STAT Ionized Calcium assay at the stated test concentrations:

Substance	Test Concentration (mmol/L)
Acetaminophen *(therapeutic)*	0.132
Acetylcysteine *(therapeutic)*	0.30 [7,8]
Ascorbate	0.34
Bromide *(therapeutic)*	2.5 [10,11,12]
β-Hydroxybutyrate	6.0 [13]

Notes:

1) Acetaminophen has been shown to interfere at a concentration proscribed by the CLSI guideline, 1.32 mmol/L, which represents a toxic concentration. Acetaminophen at 0.132 mmol/L, which represents the upper end of the therapeutic concentration, has been shown not to significantly interfere with i-STAT ionized calcium results.

2) Acetylcysteine has been tested at two levels; the CLSI recommended level and a concentration of 0.30 mmol/L. The latter is 3 times the peak plasma therapeutic concentration associated with treatment to reverse acetaminophen poisoning. APOC has not identified a therapeutic condition that would lead to levels consistent with the CLSI recommended level. Acetylcysteine at a concentration of 10.2 mmol/L decreased i-STAT ionized calcium results, while acetylcysteine at a concentration of 0.3 mmol/L did not significantly interfere with ionized calcium results.

3) Bromide has been tested at two levels; the CLSI recommended level and a therapeutic plasma concentration level of 2.5 mmol/L. The latter is the peak plasma concentration associated with halothane anesthesia, in which bromide is released. APOC has not identified a therapeutic condition that would lead to levels consistent with the CLSI recommended level. Bromide at a concentration of 37.5 mmol/L increased i-STAT ionized calcium results, while bromide at a concentration of 2.5 mmol/L did not significantly interfere with i-STAT ionized calcium results.

4) Salicylate has been shown to significantly decrease ionized calcium results at a concentration proscribed by the CLSI guideline, 4.34 mmol/L, which represents a toxic concentration.Salicylate at 0.5 mmol/L, which represents the upper end of the therapeutic concentration, has been shown to

decrease ionized calcium results by approximately 0.03 mmol/L.

5) Nithiodote (sodium thiosulfate) is indicated for the treatment of acute cyanide poisoning. The journal article titled "Falsely increased chloride and missed anion gap elevation during treatment with sodium thiosulfate" indicated that sodium thiosulfate could be used in the treatment of calciphylaxis indicating that "the highest concentration likely to be seen in plasma [is] after infusion of a 12.5 g dose of sodium thiosulfate pentahydrate. Assuming that the 12.5 g dose of sodium thiosulfate pentahydrate is distributed in a typical blood volume of 5 L with a hematocrit of 40%, the peak sodium thiosulfate plasma concentration expected is 16.7 mmol/L."[14]

*It is possible that other interfering substances may be encountered. The degree of interference at concentrations other than those listed might not be predictable.

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Abbott Point of Care Inc.
100 and 200 Abbott Park Road
Abbott Park, IL 60064 • USA

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Emergo Europe
Molenstraat 15
2513 BH, The Hague
The Netherlands

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PO$_2$ AND CALCULATED OXYGEN SATURATED/sO$_2$

PO$_2$ is measured amperometrically. The oxygen sensor is similar to a conventional Clark electrode. Oxygen permeates through a gas permeable membrane from the blood sample into an internal electrolyte solution where it is reduced at the cathode. The oxygen reduction current is proportional to the dissolved oxygen concentration.

See below for information on factors affecting results. Certain substances, such as drugs, may affect analyte levels *in vivo*.[1]

If results appear inconsistent with the clinical assessment, the patient sample should be retested using another cartridge.

Intended Use

The test for PO$_2$, as part of the i-STAT System, is intended for use in the *in vitro* quantification of oxygen partial pressure in arterial, venous, or capillary whole blood.

PO$_2$ measurements are used in the diagnosis, monitoring, and treatment of respiratory disturbances and metabolic and respiratory-based acid-base disturbances.

Contents

Each i-STAT cartridge contains one reference electrode (when potentiometric sensors are included in the cartridge configuration), sensors for the measurement of specific analytes, and a buffered aqueous calibrant solution that contains known concentrations of analytes and preservatives.

Metrological Traceability

The i-STAT System test for oxygen partial pressure measures oxygen partial pressure in arterial, venous, or capillary whole blood (dimension kPa) for *in vitro* diagnostic use. PO$_2$ values assigned to i-STAT's controls and calibration verification materials are traceable to U.S. National Institute of Standards and Technology (NIST) standard reference materials via commercially available certified specialty medical gas standards. i-STAT System controls and calibration verification materials are validated for use only with the i-STAT System and assigned values may not be commutable with other methods. Further information regarding metrological traceability is available from Abbott Point of Care Inc..

Expected Values

Test	Units*	Reportable Range	Reference Range[2]
PO$_2$	mmHg	5 – 800	80 – 105
	kPa	0.7 – 106.6	10.7 – 14.0
sO$_2$**	%	not applicable	95 – 98

*The i-STAT System can be configured with the preferred units.

** Calculated

To convert PO$_2$ results from mmHg to kPa, multiply the mmHg value by 0.133.

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The reference ranges shown are for a healthy population. Interpretation of blood gas measurements depend on the underlying condition (eg. patient temperature, ventilation, posture and circulatory status).

Clinical Significance

PO_2 (partial pressure of oxygen) is a measurement of the tension or pressure of oxygen dissolved in blood. Some causes for decreased values of PO_2 include decreased pulmonary ventilation (e.g. airway obstruction or trauma to the brain), impaired gas exchange between alveolar air and pulmonary capillary blood (e.g. bronchitis, emphysema, or pulmonary edema), and alteration in the flow of blood within the heart or lungs (e.g. congenital defects in the heart or shunting of venous blood into the arterial system without oxygenation in the lungs).

sO_2 (oxygen saturation) is the amount of oxyhemoglobin expressed as a fraction of the total amount of hemoglobin able to bind oxygen (oxyhemoglobin plus deoxyhemoglobin).

$$sO_2 = 100 \frac{(X^3 + 150X)}{X^3 + 150X + 23400}$$

$$\text{where } X = PO_2 \bullet 10^{(0.48(pH-7.4)-0.0013(HCO_3-25))}$$

sO_2 is calculated from measured PO_2 and pH and from HCO_3 calculated from measured PCO_2 and pH. However, this calculation assumes normal affinity of oxygen for hemoglobin. It does not take into account erythrocyte diphosphoglycerate (2,3-DPG) concentrations which affect the oxygen dissociation curve. The calculation also does not take into account the effects of fetal hemoglobin or dysfunctional hemoglobins (carboxy-, met-, and sulfhemoglobin). Clinically significant errors can result from incorporation of such an estimated sO_2 value for oxygen saturation in further calculations, such as shunt fraction, or by assuming the value obtained is equivalent to fractional oxyhemoglobin.

Temperature "Correction" Algorithm

PO_2 is a temperature-dependent quantity and is measured at 37°C. The PO_2 reading at a body temperature other than 37°C can be 'corrected' by entering the patient's temperature on the chart page of the analyzer. See section 12 'Procedure for Cartridge Testing' in the i-STAT 1 System Manual or section 11 'Patient and Control Sample Testing' in the i-STAT System Manual for details. In this case, blood gas results will be displayed at both 37°C and the patient's temperature. The PO_2 at the patient's temperature (T_p) is calculated as follows[3]:

$$PO_2(T_p) = PO_2 \times 10^{\frac{5.49 \times 10^{-11} PO_2{}^{3.88} + 0.071}{9.72 \times 10^{-9} PO_2{}^{3.88} + 2.30}(T_p - 37)}$$

Note: Patient temperature corrected results are only available on cartridges containing pH, PCO_2, and PO_2 sensors.

Performance Characteristics

The performance characteristics of the sensors are equivalent in all cartridge configurations.

The typical performance data summarized below was collected in a health care facility by health care professionals trained in the use of the i-STAT System and comparative method.

Precision data were collected in multiple sites as follows: Duplicates of each control fluid were tested in the morning and in the afternoon on five days for a total of 20 replicates. The averaged statistics are presented below.

Method comparison data were collected using CLSI guideline EP9-A[4]. Arterial blood samples were collected from hospital patients in 3cc blood gas syringes and were analyzed in duplicate on the i-STAT System and the comparative method within 5 minutes of each other.

Deming regression analysis[5] was performed on the first replicate of each sample. In the method comparison table, n is the number of specimens in the data set, Sxx and Syy refer to estimates of imprecision based on the duplicates of the comparative and the i-STAT methods respectively, Sy.x is the standard error of the estimate, and r is the correlation coefficient.* Method comparisons will vary from site to site due to differences in sample handling, comparative method calibration and other site specific variables.

* The usual warning relating to the use of regression analysis is summarized here as a reminder: For any analyte, "if the data is collected over a narrow range, the estimate of the regression parameters are relatively imprecise and may be biased. Therefore, predictions made from these estimates may be invalid".[6] The correlation coefficient, r, can be used as a guide to assess the adequacy of the comparative method range in overcoming this problem. As a guide, the range of data can be considered adequate if r>0.975.

Precision Data (mmHg)

Aqueous Control	Mean	SD	%CV
Level 1	65.1	3.12	4.79
Level 3	146.5	6.00	4.10

Method Comparison (mmHg)

	Radiometer ABL500	Radiometer ABL700	Bayer 845
n	45	29	30
Sxx	3.70	2.04	3.03
Syy	2.78	2.64	3.28
Slope	1.023	0.962	1.033
Int't	-2.6	1.2	-2.9
Sy.x	2.52	3.53	3.44
Xmin	----	39	31
Xmax	----	163	185
r	0.996	0.990	0.996

Factors Affecting Results*

Exposure of the sample to air will cause an increase in PO_2 when values are below 150 mmHg and a decrease in PO_2 when values are above 150 mmHg (approximate PO_2 of room air).

Standing anaerobically at room temperature will decrease pH at a rate of 0.03 per hour, will increase PCO_2 by approximately 4 mmHg per hour and will decrease PO_2 at a rate of 2–6 mmHg per hour.[6]

Do not ice samples before testing – PO_2 results may be falsely elevated in cold samples. Do not use a cold cartridge – PO_2 results may be falsely decreased if the cartridge is cold.

*It is possible that other interfering substances may be encountered. These results are representative and your results may differ somewhat due to test-to-test variation. The degree of interference at concentrations other than those listed might not be predictable.

Factors Affecting Calculated Results

sO_2 values calculated from a measured PO_2 and an assumed oxyhemoglobin dissociation curve may differ significantly from the direct measurement.[3]

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Abbott Point of Care Inc.
Abbott Park, IL 60064 • USA

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Emergo Europe
Molenstraat 15
2513 BH, The Hague
The Netherlands
Tel: (31)70 345 8570
Fax: (31)70 346 7299

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pH

pH is measured by direct potentiometry. In the calculation of results for pH, concentration is related to potential through the Nernst equation. Results are reported at 37°C.

See below for information on factors affecting results. Certain substances, such as drugs, may affect analyte levels *in vivo*.[1]

If results appear inconsistent with the clinical assessment, the patient sample should be retested using another cartridge.

Intended Use

The test for pH, as part of the i-STAT System, is intended for use in the *in vitro* quantification of pH in arterial, venous, or capillary whole blood.

pH measurements are used in the diagnosis, monitoring, and treatment of respiratory disturbances and metabolic and respiratory-based acid-base disturbances.

Contents

Each i-STAT cartridge contains one reference electrode (when potentiometric sensors are included in the cartridge configuration), sensors for the measurement of specific analytes, and a buffered aqueous calibrant solution that contains known concentrations of analytes and preservatives. For cartridges that contain a sensor for the measurement of pH, a list of reactive ingredients is indicated below:

Reactive Ingredient	Minimum Quantity
Hydrogen Ion (H^+)	6.66 pH

Metrological Traceability

The i-STAT System test for pH measures the hydrogen ion amount-of-substance concentration in the plasma fraction of arterial, venous, or capillary whole blood (expressed as the negative logarithm of the relative molal hydrogen ion activity) for *in vitro* diagnostic use. pH values assigned to i-STAT's controls and calibration verification materials are traceable to the U.S. National Institute of Standards and Technology (NIST) standard reference materials SRMs 186-I, 186-II, 185, and 187. i-STAT System controls and calibration verification materials are validated for use only with the i-STAT System and assigned values may not be commutable with other methods. Further information regarding metrological traceability is available from Abbott Point of Care Inc..

Expected Values

Test/Abbreviation	Units	Reportable Range	Reference Range	
pH		6.50 – 8.20	7.35 – 7.45[2] (arterial)	7.31 – 7.41* (venous)

* Calculated from Siggaard-Andersen nomogram.

Venous samples normally measure 0.01 – 0.03 pH units lower than arterial samples.

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The reference range programmed into the analyzer and shown above is intended to be used as a guide for the interpretation of results. Since reference ranges may vary with demographic factors such as age, gender and heritage, it is recommended that reference ranges be determined for the population being tested.

Clinical Significance

pH is an index of the acidity or alkalinity of the blood with an arterial pH of <7.35 indicating an acidemia and >7.45 alkalemia.[3]

Temperature "Correction" Algorithm

pH is a temperature-dependent quantity that is measured on the i-STAT System at 37°C. The pH reading at a body temperature other than 37°C can be 'corrected' by entering the patient's temperature on the chart page of the analyzer. See section 12 'Procedure for Cartridge Testing' in the i-STAT 1 System Manual or section 11 'Patient and Control Sample Testing' in the i-STAT System Manual for details. In this case, blood gas results will be displayed at both 37°C and the patient's temperature. The pH at the patient's temperature (T_p) is calculated as follows[4]:

$$pH(T_p) = pH - 0.0147(T_p - 37) + 0.0065(7.4 - pH)(T_p - 37)$$

Note: Patient temperature corrected results are only available on cartridges containing pH, $P\mathrm{CO}_2$, and $P\mathrm{O}_2$ sensors.

Performance Characteristics

The performance characteristics of the sensors are equivalent in all cartridge configurations.

The typical performance data summarized below was collected in health care facilities by health care professionals trained in the use of the i-STAT System and comparative methods.

Precision data were collected in multiple sites as follows: Duplicates of each control fluid were tested in the morning and in the afternoon on five days for a total of 20 replicates. The averaged statistics are presented below.

Method comparison data were collected using CLSI guideline EP9-A[5]. Venous blood samples were collected in evacuated tubes and arterial samples were collected in blood gas syringes with lithium heparin anticoagulant. All sample were analyzed in duplicate on the i-STAT System and on the comparative methods within 10 minutes of each other. Arterial blood samples were collected from hospital patients in 3 mL blood gas syringes and were analyzed in duplicate on the i-STAT-System and the comparative method within 5 minutes of each other.

Deming regression analysis[6] was performed on the first replicate of each sample. In the method comparison table, n is the number of specimens in the data set, Sxx and Syy refer to estimates of imprecision based on the duplicates of the comparative and the i-STAT methods respectively, Sy.x is the standard error of the estimate, and r is the correlation coefficient.*

Method comparisons will vary from site to site due to differences in sample handling, comparative method calibration and other site specific variables.

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* The usual warning relating to the use of regression analysis is summarized here as a reminder: For any analyte, "if the data is collected over a narrow range, the estimate of the regression parameters are relatively imprecise and may be biased. Therefore, predictions made from these estimates may be invalid".[4] The correlation coefficient, r, can be used as a guide to assess the adequacy of the comparative method range in overcoming this problem. As a guide, the range of data can be considered adequate if r>0.975.

Precision Data

Aqueous Control	Mean	SD	%CV
Level 1	7.165	0.005	0.08
Level 3	7.656	0.003	0.04

Method Comparison

	IL BGE	Radiometer ICA 1	Nova STAT Profile 5	Radiometer ABL500
n	62	47	57	45
Sxx	0.005	0.011	0.006	0.004
Syy	0.009	0.008	0.008	0.008
Slope	0.974	1.065	1.058	1.0265
Int't	0.196	-0.492	-0.436	-0.1857
Sy.x	0.012	0.008	0.010	0.0136
Xmin	7.210	7.050	7.050	
Xmax	7.530	7.570	7.570	
r	0.985	0.990	0.9920	.986

Factors Affecting Results*

Venous stasis (prolonged tourniquet application) and forearm exercise may decrease pH due to localized production of lactic acid. Exposing the sample to air will cause an increase in pH due to the loss of CO_2. pH decreases on standing anaerobically at room temperature at a rate of 0.03 pH units per hour.[3]

Hemodilution of the plasma by more than 20% associated with priming cardiopulmonary bypass pumps, plasma volume expansion or other fluid administration therapies using certain solutions may cause clinically significant error on sodium, chloride, ionized calcium and pH results. These errors are associated with solutions that do not match the ionic characteristics of plasma. To minimize these errors when hemodiluting by more than 20%, use physiologically balanced multi-electrolyte solutions containing low-mobility anions (e.g., gluconate).

*It is possible that other interfering substances may be encountered. These results are representative and your results may differ somewhat due to test-to-test variation. The degree of interference at concentrations other than those listed might not be predictable.

References

1. D.S. Young, Effects of Drugs on Clinical Laboratory Tests, 3rd ed. (Washington, DC: American Association of Clinical Chemistry, 1990).

2. P.C. Painter, J.Y. Cope, J.L. Smith, "Reference Ranges, Table 41–20" in Tietz Textbook of Clinical Chemistry—Second Edition, C.A. Burtis and E.R. Ashwood, eds. (Philadelphia: W.B. Saunders Company, 1994).

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4. CLSI. *Blood Gas and pH Analysis and Related Measurements; Approved Guideline.* CLSI document C46-A [ISBN 1-56238-444-9]. CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898, USA 2001.

5. CLSI. *Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline.* CLSI document EP9-A [ISBN 1-56238-283-7]. CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898, USA 1995.

6. P.J. Cornbleet and N. Gochman, "Incorrect Least-Squares Regression Coefficients in Method-Comparison Analysis," Clinical Chemistry 25:3, 432 (1979).

Abbott Point of Care Inc.
100 and 200 Abbott Park Road
Abbott Park, IL 60064 • USA

EC REP

Emergo Europe
Molenstraat 15
2513 BH, The Hague
The Netherlands

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PCO$_2$ AND CALCULATED VALUES FOR HCO$_3$, BASE EXCESS AND ANION GAP

PCO$_2$ is measured by direct potentiometry. In the calculation of results for PCO$_2$, concentration is related to potential through the Nernst equation. Results are reported at 37°C.

Calculated Values

When a cartridge includes sensors for both pH and PCO$_2$, bicarbonate (HCO$_3$), total carbon dioxide (TCO$_2$) and base excess (BE) are calculated.[1]

$$\log HCO_3 = pH + \log PCO_2 - 7.608$$

$$BE_{ecf} = HCO_3 - 24.8 + 16.2 (pH - 7.4)$$

$$BE_b = (1 - 0.014*Hb) * [HCO_3 - 24.8 + (1.43 * Hb + 7.7) * (pH - 7.4)]$$

Anion Gap is calculated in the EC8+ and CHEM8+ cartridges as follows:

$$Anion\ Gap\ (EC8+) = (Na + K) - (Cl + HCO_3)$$

$$Anion\ Gap\ (CHEM8+) = (Na + K) - (Cl + (TCO_2 - 1))$$

See below for information on factors affecting results. Certain substances, such as drugs, may affect analyte levels *in vivo*.[2] If results appear inconsistent with the clinical assessment, the patient sample should be retested using another cartridge.

Intended Use

The test for PCO$_2$, as part of the i-STAT® System, is intended for use in the *in vitro* quantification of carbon dioxide partial pressure in arterial, venous, or capillary whole blood.

PCO$_2$ measurements are used in the diagnosis, monitoring, and treatment of respiratory disturbances and metabolic and respiratory-based acid-base disturbances.

Bicarbonate is used in the diagnosis and treatment of numerous potentially serious disorders associated with changes in body acid-base balance.

Contents

Each i-STAT cartridge contains one reference electrode (when potentiometric sensors are included in the cartridge configuration), sensors for the measurement of specific analytes, and a buffered aqueous calibrant solution that contains known concentrations of analytes and preservatives. For cartridges that contain a sensor for the measurement of PCO$_2$, a list of reactive ingredients is indicated below:

Reactive Ingredient	Minimum Quantity
Carbon Dioxide (CO$_2$)	25.2 mmHg

Metrological Traceability

The i-STAT System test for carbon dioxide partial pressure measures carbon dioxide partial pressure in arterial, venous, or capillary whole blood (dimension kPa) for *in vitro* diagnostic use. PCO$_2$ values assigned to i-STAT's controls and calibration verification materials are traceable to U.S. National Institute of Standards and Technology (NIST) standard reference materials via commercially available certified specialty medical gas standards. i-STAT System controls and calibration verification materials are validated for use

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only with the i-STAT System and assigned values may not be commutable with other methods. Further information regarding metrological traceability is available from Abbott Point of Care Inc..

Expected Values

Test/Abbreviation	Units*	Reportable Range	Reference Range	
			(arterial)	(venous)
Partial Pressure Carbon Dioxide/PCO_2	mmHg	5 – 130	35 – 45[3]	41 – 51
	kPa	0.67 – 17.33	4.67 – 6.00	5.47 – 6.80
Bicarbonate/HCO_3	mmol/L	1.0 – 85.0	22 – 26**	23 – 28**
Base Excess/BE	mmol/L	(-30) – (+30)	(-2) – (+3)[3]	(-2) – (+3)[3]
Anion Gap/AnGap	mmol/L	(-10) – (+99)	10 – 20[3]	10 – 20[3]

*The i-STAT System can be configured with the preferred units.
**Calculated from Siggaard-Andersen nomogram.[4]

To convert PCO_2 results from mmHg to kPa, multiply the mmHg value by 0.133.

The reference ranges programmed into the analyzer and shown above are intended to be used as guides for the interpretation of results. Since reference ranges may vary with demographic factors such as age, gender and heritage, it is recommended that reference ranges be determined for the population being tested.

Clinical Significance

PCO_2 along with pH is used to assess acid-base balance. PCO_2 (partial pressure of carbon dioxide), the respiratory component of acid-base balance, is a measure of the tension or pressure of carbon dioxide dissolved in the blood. PCO_2 represents the balance between cellular production of CO_2 and ventilatory removal of CO_2 and a change in PCO_2 indicates an alteration in this balance. Causes of primary respiratory acidosis (increase in PCO_2) are airway obstruction, sedatives and anesthetics, respiratory distress syndrome, and chronic obstructive pulmonary disease. Causes of primary respiratory alkalosis (decreased PCO_2) are hypoxia (resulting in hyperventilation) due to chronic heart failure, edema and neurologic disorders, and mechanical hyperventilation.

HCO_3 (bicarbonate), the most abundant buffer in the blood plasma, is an indicator of the buffering capacity of blood. Regulated primarily by the kidneys, HCO_3 is the metabolic component of acid-base balance. Causes of primary metabolic acidosis (decrease in HCO_3) are ketoacidosis, lactate acidosis (hypoxia), and diarrhea. Causes of primary metabolic alkalosis (increase in HCO_3) are vomiting and antacid treatment.

Base excess of the extracellular fluid or standard base excess is defined as the concentration of titratable base minus the concentration of titratable acid when titrating the average intracellular fluid (plasma plus interstitial fluid) to an arterial plasma pH of 7.40 at PCO_2 of 40 mmHg at 37°C. Excess concentration of base in the average ECF remains virtually constant during acute changes in the PCO_2 and reflects only nonrespiratory component of pH-disturbances.

Anion gap is reported as the difference between the commonly measured cations sodium and potassium and the commonly measured anions chloride and bicarbonate. The size of the gap reflects unmeasured cations and anions and is therefore an analytical gap. Physiologically, a deficit of anions cannot exist. While relatively nonspecific, anion gap is useful for the detection of organic acidosis due to an increase in anions that are difficult to measure. Anion gap can be used to classify metabolic acidosis into high and normal anion gap types. Anion gap may be only slightly increased in diarrhea and renal failure, but elevated (often >25) due to an increase in organic anions in lactic acidosis, ketoacidosis (alcoholic, diabetic, starvation) and uremia, an increase in inorganic anions in uremia, and an increase in anions from drugs such a salicylate and carbenicillin or toxins such as methanol and ethanol.

Temperature "Correction" Algorithm

PCO_2 is a temperature-dependent quantity and is measured at 37°C. The PCO_2 reading at a body temperature other than 37°C can be 'corrected' by entering the patient's temperature on the chart page of the analyzer. See section 12 'Procedure for Cartridge Testing' in the i-STAT 1 System Manual or section 11 'Patient and Control Sample Testing' in the i-STAT System Manual for details. In this case, blood gas results will be displayed at both 37°C and the patient's temperature. The PCO_2 at the patient's temperature (T_p) is calculated as follows:[1]

$$PCO_2(T_p) = PCO_2 \times 10^{0.019(T_p - 37)}$$

Note: Patient temperature corrected results are available only on cartridges containing pH, PCO_2, and PO_2 sensors.

Performance Characteristics

The performance characteristics of the sensors are equivalent in all cartridge configurations.

The typical performance data summarized below were collected in a health care facility by health care professionals trained in the use of the i-STAT System and comparative methods.

Precision data were collected in multiple sites as follows: Duplicates of each control fluid were tested in the morning and in the afternoon on five days for a total of 20 replicates. The averaged statistics are presented below.

Method comparison data were collected using CLSI guideline EP9-A.[5] Venous blood samples were collected in blood gas syringes. All samples were analyzed in duplicate on the i-STAT System and on the comparative methods within 10 minutes of each other. Arterial blood samples were collected from hospital patients in 3 cc blood gas syringes and were analyzed in duplicate on the i-STAT System and the comparative method within 5 minutes of each other.

Deming regression analysis[6] was performed on the first replicate of each sample. In the method comparison table, n is the number of specimens in the data set, Sxx and Syy refer to estimates of imprecision based on the duplicates of the comparative and the i-STAT methods respectively, Sy.x is the standard error of the estimate, and r is the correlation coefficient.*

Method comparisons will vary from site to site due to differences in sample handling, comparative method calibration and other site specific variables.

* The usual warning relating to the use of regression analysis is summarized here as a reminder: For any analyte, "if the data is collected over a narrow range, the estimate of the regression parameters are relatively imprecise and may be biased. Therefore, predictions made from these estimates may be invalid".[7] The correlation coefficient, r, can be used as a guide to assess the adequacy of the comparative method range in overcoming this problem. As a guide, the range of data can be considered adequate if r>0.975.

Precision Data (mmHg)

Aqueous Control	Mean	SD	%CV
Level 1	63.8	1.57	2.5
Level 3	19.6	0.40	2.0

Method Comparison (mmHg)

	$P\text{CO}_2$ IL BGE	$P\text{CO}_2$ Radiometer ABL500
n	62	29
Sxx	0.69	0.74
Syy	1.24	0.53
Slope	1.003	1.016
Int't	-0.8	1.1
Sy.x	1.65	0.32
Xmin	30.4	28
Xmax	99.0	91
r	0.989	0.999

Factors Affecting Results*

Exposing the sample to air allows CO_2 to escape which causes $P\text{CO}_2$ to decrease and pH to increase and HCO_3 and TCO_2 to be under-estimated. The use of partial-draw tubes (evacuated tubes that are adjusted to draw less than the tube volume, e.g., a 5 cc tube with enough vacuum to draw only 3 cc) is not recommended for use with the i-STAT System because of the potential for decreased measured $P\text{CO}_2$ results and calculated HCO_3 and TCO_2 values. Under-filling blood collection tubes may also cause decreased $P\text{CO}_2$ results. Care must also be taken to eliminate "bubbling" of the sample with a pipette when filling a cartridge to avoid the loss of CO_2 in the blood.

Allowing blood to stand (without exposure to air) before testing allows $P\text{CO}_2$ to increase and pH to decrease, which will cause HCO_3 and TCO_2 to be over-estimated, due to metabolic processes.

For patients administered propofol (Diprivan®) or thiopental sodium (syn. thiomebumal sodium, penthiobarbital sodium, thiopentone sodium, thionembutal, Pentothal Sodium®, Nesdonal Sodium®, Intraval Sodium®, Trapanal®, and Thiothal Sodium[7]), i-STAT recommends the use of G3+, CG4+, CG8+, EG6+ and EG7+ cartridges, which are free from clinically significant interference at all relevant therapeutic doses. i-STAT does not recommend the use of EC8+ cartridges for patients receiving propofol (Diprivan®) or thiopental sodium.

* It is possible that other interfering substances may be encountered. These results are representative and your results may differ somewhat due to test-to-test variation. The degree of interference at concentrations other than those listed might not be predictable.

References

1. CLSI. *Blood Gas and pH Analysis and Related Measurements; Approved Guideline.* CLSI document C46-A [ISBN 1-56238-444-9]. CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898, USA 2001.

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3. P.C. Painter, J.Y. Cope, J.L. Smith, "Reference Ranges, Table 41–20" in Tietz Textbook of Clinical Chemistry—Second Edition, C.A. Burtis and E.R. Ashwood, eds. (Philadelphia: W.B. Saunders Company, 1994).

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Abbott Point of Care Inc.
Abbott Park, IL 60064 • USA

EC REP

Emergo Europe
Molenstraat 15
2513 BH, The Hague
The Netherlands
Tel: (31)70 345 8570
Fax: (31)70 346 7299

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TOTAL CARBON DIOXIDE/ (TCO$_2$)

Intended Use

The test for TCO$_2$, as part of the i-STAT System, is intended for use in the *in vitro* quantification of total carbon dioxide in arterial, venous, or capillary whole blood.

Carbon dioxide is used in the diagnosis, monitoring, and treatment of numerous potentially serious disorders associated with changes in body acid-base balance.

Method Explanation

The measured TCO$_2$ test method is calibrated to the International Federation of Clinical Chemistry (IFCC) TCO$_2$ reference method[1] with an algorithm, based on the Henderson-Hasselbalch equation, which uses pH, PCO$_2$, and ionic strength (Na) measurements.

Contents

Each i-STAT cartridge contains one reference electrode (when potentiometric sensors are included in the cartridge configuration), sensors for the measurement of specific analytes, and a buffered aqueous calibration solution that contains known concentrations of analytes and preservatives. For cartridges that contains sensors for the measurement of TCO$_2$, a list of reactive ingredients is indicated below:

Reactive Ingredient	Minimum Quantity
Carbon Dioxide (CO$_2$)	25.2 mmHg

Metrological Traceability

The i-STAT System test for total carbon dioxide (TCO$_2$) measures the amount-of-substance total concentration of all forms of carbon dioxide in the plasma fraction of arterial, venous, or capillary whole blood (dimension mmol L^{-1}) for *in vitro* diagnostic use. TCO$_2$ values assigned to i-STAT System controls and calibration verification materials are traceable to the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) Reference Measurement Procedure for Substance Concentration Determination for Total Carbon Dioxide in Blood, Plasma or Serum.[1] i-STAT System controls and calibration verification materials are validated for use only with the i-STAT System and assigned values may not be commutable with other methods. Further information regarding metrological traceability is available from Abbott Point of Care Inc..

Expected Values

TEST	UNITS	REPORTABLE RANGE	REFERENCE RANGE	
			(arterial)	*(venous)*
Total Carbon Dioxide/TCO$_2$	mmol/L	5 – 50	23 – 27*	24 – 29*

*Calculated from Siggard-Andersen nomogram.[2]

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The reference ranges programmed into the analyzer and shown above are intended to be used as guides for the interpretation of results. Since reference ranges may vary with demographic factors such as age, gender, and heritage, it is recommended that reference ranges be determined for the population being tested.

Clinical Significance

TCO_2 is a measure of carbon dioxide which exists in several states: CO_2 in physical solution or loosely bound to proteins, bicarbonate (HCO_3) or carbonate (CO_3) anions, and carbonic acid (H_2CO_3). Measurement of TCO_2 as part of an electrolyte profile is useful chiefly to evaluate HCO_3 concentration. TCO_2 and HCO_3 are useful in the assessment of acid-base imbalance (along with pH and PCO_2) and electrolyte imbalance.

Calculated and Measured (Traceable) TCO_2

The calculated TCO_2 provided by the i-STAT System is determined from the measured and reported values of pH and PCO_2 according to a simplified and standardized form of the Henderson-Hasselbalch equation.[3]

$$TCO_2 = HCO_3 + 0.03\ PCO_2$$

This calculated TCO_2 measurement is metrologically traceable to the i-STAT pH and PCO_2 measurements, which are in turn traceable to primary standard reference materials for pH and PCO_2. Like all calculated parameters reported by the i-STAT System, the user can independently determine TCO_2 values from the reported pH and PCO_2 measurements using a combination of the equation for HCO_3 given in the PCO_2 Cartridge and Test Information (CTI) sheet, and the equation for TCO_2 above.

On the CHEM8+ cartridge, TCO_2 is metrologically traceable to the IFCC TCO_2 reference method. The implication of direct traceability to this TCO_2 reference method – and not to pH and PCO_2 standard reference materials – is subtle but significant: the CHEM8+ is independent of the pH and PCO_2 traceability. Given the metrological traceability of the CHEM8+ TCO_2 measurement, the traceable TCO_2 is considered to be a measured analyte

Performance Characteristics

Precision data were collected in multiple sites following the protocol recommended by Abbott Point of Care. The means, SDs and CVs from 20 replicates at each site were averaged. The average statistics are presented below.

Method comparison data were collected using CLSI guideline EP9-A[4]. Venous blood samples were collected in lithium heparin evacuated tubes from hospital patients. The whole blood samples were run in duplicate on the i-STAT System. The samples were then centrifuged to obtain plasma and analyzed in duplicate on the comparative instrument. All samples were analyzed on both methods within 15 minutes of each other.

Deming regression analysis[5] was performed on the first replicate of each sample. In the method comparison table, n is the number of specimens in the first data set. Sxx and Syy refer to the estimates of imprecision based on the duplicates of the comparative and the i-STAT methods respectively. Sy.x is the standard error of the estimate, and r is the correlation coefficient.*

Method comparisons may vary from site to site due to differences in sample handling, comparative method calibration and other site specific variables. For TCO_2, values measured on serum or plasma by chemistry analyzers may be slightly lower than TCO_2 calculated from pH and PCO_2 due to loss of CO_2 during non-anaerobic handling.[6] Up to 6 mmol/L CO_2 can be lost per hour by exposure of the sample to air.[7]

*The usual warning relating to the use of regression analysis is summarized here as a reminder. For any analyte, "if the data is a narrow range, the estimate of the regression parameters are relatively imprecise and may be biased. Therefore, predictions made from estimates may be invalid",[4] The correlation coefficient, r, can be used as a guide to assess the adequacy of the comparative method ranges in overcoming the problem. As a guide, the range of data can be considered adequate if r>0.975.

Precision Data (mmol/L)

Aqueous Control	Mean	SD	%CV
Level 1	17.4	0.62	3.6
Level 3	34.6	0.62	1.8

Method Comparison (mmol/L)

	TCO_2 (Calculated) IL BGE	TCO_2 (Calculated) Beckman Coulter CX®3	TCO_2 (Measured) Beckman Coulter LX®20
n	62	51	35
Sxx	0.40	0.55	0.48
Syy	0.84	0.55	0.60
Slope	1.136	1.155	1.152
Int't	-4.1	-2.6	-1.5
Sy.x	1.38	1.56	0.96
Xmin	19.3	18.3	21
Xmax	43.9	36.1	35
r	0.965	0.935	0.943

Cartridge Comparison

Performance characteristics for TCO_2 are equivalent in all cartridge configurations. System difference analysis was performed on 40 patient samples using the i-STAT CHEM8+ and i-STAT EC8+ cartridges. In the 14-30 mmol/L range, the average difference was -0.7 mmol/L.

Factors Affecting Results*

Exposing the sample to air allows CO_2 to escape which causes TCO_2 to be under-estimated. The use of partial draw tubes (evacuated tubes that are adjusted to draw less than the tube volume, e.g. a 5 mL tube with enough vacuum to draw only 3 mL) is not recommended for use with the i-STAT System because of the potential for decreased TCO_2 values. Under-filling blood collection tubes may also cause decreased TCO_2 results. Care must also be taken to eliminate "bubbling" of the sample with a pipette when filling a cartridge to avoid the loss of CO_2 in the blood.

Allowing blood samples to stand (without exposure to air) before testing allows TCO_2 to be over-estimated, due to metabolic processes.

*It is possible that other interfering substances may be encountered.

References

1. IFCC Reference Measurement Procedure for Substance Concentration Determination for Total Carbon Dioxide in Blood, Plasma or Serum (IFCC 2001/3). Clin. Chem. Lab Med., 39(3), 2001.

2. E.L. Pruden, O. Siggard-Andersen, and N.W. Tietz, Blood Gases and pH, in Tietz Textbook of Clinical Chemistry, Second Edition, ed. C.A. Burtis and E.R. Ashwood. (Philadelphia: W.B. Saunders Company, 1994).

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Abbott Point of Care Inc.
Abbott Park, IL 60064 • USA

EC REP

Emergo Europe
Molenstraat 15
2513 BH, The Hague
The Netherlands
Tel: (31)70 345 8570
Fax: (31)70 346 7299

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CREATININE/CREA

Creatinine is measured amperometrically. Creatinine is hydrolyzed to creatine in a reaction catalyzed by the enzyme creatinine amidohydrolase. Creatine is then hydrolyzed to sarcosine in a reaction catalyzed by the enzyme creatine amidinohydrolase. The oxidation of sarcosine, catalyzed by the enzyme sarcosine oxidase, produces hydrogen peroxide (H_2O_2). The liberated hydrogen peroxide is oxidized at the platinum electrode to produce a current which is proportional to the sample creatinine concentration.
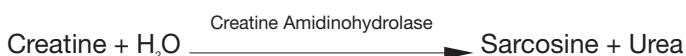
$$\text{Creatinine} + H_2O \xrightarrow{\text{Creatinine Amidohydrolase}} \text{Creatine}$$

$$\text{Creatine} + H_2O \xrightarrow{\text{Creatine Amidinohydrolase}} \text{Sarcosine} + \text{Urea}$$

$$\text{Sarcosine} + O_2 + H_2O \xrightarrow{\text{Sarcosine Oxidase}} \text{Glycine} + \text{Formaldehyde} + H_2O_2$$

$$H_2O_2 \longrightarrow O_2 + 2H^+ + 2e^-$$

See below for information on factors affecting results. Certain substances, such as drugs, may affect analyte levels *in vivo*.[1]

If results appear inconsistent with the clinical assessment, the patient sample should be retested using another cartridge.

INTENDED USE

The test for creatinine, as part of the i-STAT® System, is for the quantitative determination of creatinine in whole blood on the i-STAT handheld.

Creatinine measurements are used in the diagnosis and treatment of renal diseases, in monitoring renal dialysis, and as a calculation basis for measuring other urine analytes.

Contents

Each i-STAT cartridge contains one reference electrode (when potentiometric sensors are included in the cartridge configuration), sensors for the measurement of specific analytes, and a buffered aqueous calibrant solution that contains known concentrations of analytes and preservatives. For cartridges that contain a sensor for the measurement of creatinine, a list of reactive ingredients is indicated below:

Reactive Ingredient	Biological Source	Minimum Quantity
Creatinine	N/A	158.4 µmol/L
Creatine Amidinohydrolase	*Actinobacillus* spp.	0.01 IU
Creatinine Amidohydrolase	Microbial	0.02 IU
Sarcosine Oxidase	Microbial	0.001 IU

Metrological Traceability

The i-STAT System test for creatinine measures creatinine amount-of-substance concentration in the

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plasma fraction of arterial, venous, or capillary whole blood (dimension µmol L^{-1}) for *in vitro* diagnostic use. Creatinine values assigned to i-STAT's controls and calibration verification materials are traceable to the U.S. National Institute of Standards and Technology (NIST) standard reference material SRM967. i-STAT System controls and calibration verification materials are validated for use only with the i-STAT System and assigned values may not be commutable with other methods. Further information regarding metrological traceability is available from Abbott Point of Care Inc.

Expected Values

Test/Abbreviation	Units*	Reportable Range	Reference Range
Creatinine/Crea	mg/dL	0.2 – 20.0	0.6 – 1.3[2]
	µmol/L	18 – 1768	53 – 115

To convert a creatinine result from mg/dL to µmol/L, multiply the mg/dL value by 88.4.

The i-STAT reference ranges for whole blood listed above are similar to reference ranges derived from serum or plasma measurements with standard laboratory methods.

The reference range programmed into the analyzer and shown above is intended to be used as a guide for the interpretation of results. Since reference ranges may vary with demographic factors such as age, gender and heritage, it is recommended that reference ranges be determined for the population being tested.

* The i-STAT System can be configured with the preferred units.

Clinical Significance

Elevated levels of creatinine are mainly associated with abnormal renal function and occur whenever there is a significant reduction in glomerular filtration rate or when urine elimination is obstructed. The concentration of creatinine is a better indicator of renal function than urea or uric acid because it is not affected by diet, exercise, or hormones.

The creatinine level has been used in combination with BUN to differentiate between prerenal and renal causes of an elevated urea/BUN.

Performance Characteristics

The typical performance data summarized below were collected in health care facilities by professionals trained in the use of the i-STAT System and comparative methods. Clinical settings vary and some may require different performance characteristics to assess renal function status than others (e.g., medication dosing, intravenous contrast use, and outpatient clinic). If deemed necessary by a health care facility, performance data should be obtained in specific clinical settings to assure patients' needs are met.

Precision data were collected in multiple sites following the protocol recommended by Abbott Point of Care. The means, SDs and CVs from 20 replicates at each site were averaged. The average statistics are presented below.

Method comparison data were collected using CLSI guideline EP9-A.[3] Venous blood samples, collected in lithium or sodium heparin Vacutainer® tubes, and arterial blood samples, collected in blood gas syringes, were analyzed in duplicate on the i-STAT System. A portion of each specimen was centrifuged, and the separated plasma was analyzed on the comparative method.

Deming regression analysis[4] was performed on the first replicate of each sample. In the method comparison table, n is the number of specimens in the data set, Sxx and Syy refer to the estimates of imprecision based on the duplicates of the comparative and the i-STAT methods respectively, Sy.x is the standard error of the estimate, and r is the correlation coefficient.*

*The usual warning relating to the use of regression analysis is summarized here as a reminder. For any analyte, "if the data are collected over a narrow range, the estimate of the regression parameters is relatively imprecise and may be biased. Therefore, predictions made from these estimates may be invalid."[4] The correlation coefficient, r, can be used as a guide to assess the adequacy of the comparative method range in overcoming this problem. As a guide, the range of data can be considered adequate for r >0.975.

Precision Data (mg/dL)

Aqueous Control	Mean	SD	%CV
Level 1	4.33	0.131	3.0
Level 3	0.81	0.039	4.8

Method Comparison (mg/dL)

	Roche Integra 800	Beckman LX20	J & J Vitros 950	Dade Dimension RxL
n	30	58	31	36
Sxx	0.029	0.141	0.04	0.04
Syy	0.112	0.143	0.12	0.06
Slope	0.929	0.960	0.948	0.964
Int't	0.237	0.022	0.206	0.100
Syx	0.204	0.261	0.165	0.123
Xmin	0.4	0.7	0.5	0.5
Xmax	10.3	20.0	7.2	5.7
r	0.997	0.996	0.991	0.986

Cartridge Comparison

The performance characteristics of the sensors are equivalent in all cartridge configurations. System difference analysis was performed on 39 patient samples using the i-STAT CHEM8+ and i-STAT Crea cartridges. In the 0.42-2.50 mg/dL range, the average difference was -0.01. In the 2.50-9.08 mg/dL range, the average difference was -0.04.

Factors affecting results*

Interference studies were based on CLSI guideline EP7-A2.[5] Test concentrations used were as per the CLSI guideline unles otherwise indicated.

When added to a plasma pool the following substances (at the concentrations indicated) were found to interfere with the i-STAT Creatinine assay:

Substance	Test Concentration (mmol/L)	Interference
Acetaminophen	1.32	Increased i-STAT creatinine results. See Note below.
Acetylcysteine	10.2	Increased i-STAT creatinine results. See Note below.
Ascorbate	0.34	Increased i-STAT creatinine results by up to 0.3 mg/dL.
Bromide (*therapeutic*)	2.5 [6,7,8]	Increased i-STAT creatinine results. See Note below.
Creatine	0.382	Increased i-STAT creatinine results by up to 0.3 mg/dL. See Note below.
Glycolic Acid	10.0	Decreased i-STAT creatinine results. Use another method.
Hydroxyurea	0.92	Increased i-STAT creatinine results. Use another method.
Nithiodote (sodium thiosulfate)	16.7[13]	Increased i-STAT creatinine results. See Note below.

The following substances are known not to significantly interfere with the i-STAT Creatinine assay at the stated test concentrations:

Substance	Test Concentration (mmol/L)
Acetaldehyde	0.045 [9]
Acetaminophen (therapeutic)	0.132 [9]
Acetylcysteine (therapeutic)	0.3 [10,11]
Bicarbonate	35.0
Bilirubin	0.342
Calcium Chloride	5.0
Dopamine	0.006
Formaldehyde	0.133 [9]
β–Hydroxybutyrate	6.0 [12]
Lactate	6.6
Methyldopa	0.071
Pyruvate	0.31
Salicylate	4.34
Uric Acid	1.4

Notes:

1) The normal range of creatine concentration in plasma is 0.17–0.70 mg/dL (13 – 53 µmol/L) in males and 0.35 – 0.93 mg/dL (27 – 71 µmol/L) in females.[9] Creatine may be elevated in patients using creatine supplements, experiencing muscle trauma or other primary or secondary myopathies, taking statins for hyperlipidemia control, or in patients with hyperthyroidism or a rare genetic defect of the creatine trans-porter protein.

2) Hydroxyurea is a DNA synthesis inhibitor used in the treatment of various forms of cancer, sickle cell anemia, and HIV infection. This drug is used to treat malignancies including melanoma, metastatic ovar-ian cancer, and chronic myelogenous leukemia. It is also used in the treatment of polycythemia vera, thrombocythemia, and psoriasis. At typical doses ranging from 500 mg to 2 g/day, concentrations of hydroxyurea in patients' blood may be sustained at approximately 100 to 500 µmol/L. Higher concentra-tions may be observed soon after dosing or at higher therapeutic doses.

3) Acetaminophen has been shown to interfere at a concentration proscribed by the CLSI guideline, 1.32 mmol/L, which represents a toxic concentration. Acetaminophen at 0.132 mmol/L, which represents the upper end of the therapeutic concentration, has been shown not to significantly interfere with i-STAT creatinine results.

4) Acetylcysteine has been tested at two levels: the CLSI recommended level and a concentration of 0.30 mmol/L. The latter is 3 times the peak plasma therapeutic concentration associated with treatment to reverse acetaminophen poisoning. APOC has not identified a therapeutic condition that would lead to levels consistent with the CLSI recommended level. Acetylcysteine at a concentration of 10.2 mmol/L increased i-STAT creatinine results, while acetylcysteine at a concentration of 0.3 mmol/L did not signifi-cantly interfere with i-STAT creatinine results.

5) Bromide has been tested at two levels: the CLSI recommended level and a therapeutic plasma concentration level of 2.5 mmol/L. The latter is the peak plasma concentration associated with halothane anesthesia, in which bromide is released. APOC has not identified a therapeutic condition that would lead to levels consistent with the CLSI recommended level. Bromide tested at concentrations of 2.5 and 37.5 mmol/L interfered with i-STAT creatinine results.

6) The dependence of the i-STAT creatinine with respect to Carbon Dioxide (CO_2) is as follows:

For Crea values below 2 mg/dL:
For PCO_2 values above 40 mmHg, the values are increased by 6.9% for every 10 mmHg
For PCO_2 values below 40 mmHg, the values are decreased by 6.9% for every 10 mmHg
$[Cr]corrected = [Cr]istat \times \{ 1 - (0.069 \times [(PCO_2 - 40)/10]) \}$

For Crea values above 2 mg/dL:
For PCO_2 values above 40, the values are decreased by 3.7% for every 10 mmHg
For PCO_2 values below 40, the values are increased by 3.7% for every 10 mmHg
$[Cr]corrected = [Cr]istat \times \{ 1 - (0.037 \times [(40 - PCO_2)/10]) \}$

7) Nithiodote (sodium thiosulfate) is indicated for the treatment of acute cyanide poisoning. The journal article titled "Falsely increased chloride and missed anion gap elevation during treatment with sodium thiosulfate" indicated that sodium thiosulfate could be used in the treatment of calciphylaxis indicating that "the highest concentration likely to be seen in plasma [is] after infusion of a 12.5 g dose of sodium thiosulfate pentahydrate. Assuming that the 12.5 g dose of sodium thiosulfate pentahydrate is distributed in a typical blood volume of 5 L with a hematocrit of 40%, the peak sodium thiosulfate plasma concentration expected is 16.7 mmol/L."[13]

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*It is possible that other interfering substance may be encountered. The degree of interference at concentrations other than those listed might not be predictable.

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LACTATE/LAC

Lactate is measured amperometrically. The enzyme lactate oxidase, immobilized in the lactate biosensor, selectively converts lactate to pyruvate and hydrogen peroxide (H_2O_2). The liberated hydrogen peroxide is oxidized at a platinum electrode to produce a current which is proportional to the sample lactate concentration.

$$L\text{-Lactate} + O_2 \xrightarrow{\text{Lactate Oxidase}} \text{Pyruvate} + H_2O_2$$

$$H_2O_2 \xrightarrow{\text{Platinum electrode}} 2H^+ + O_2 + 2e^-$$

See below for information on factors affecting results. Certain substances, such as drugs, may affect analyte levels *in vivo.*[1]

If results appear inconsistent with the clinical assessment, the patient sample should be retested using another cartridge.

Intended Use

The test for lactate, as part of the i-STAT System, is intended for use in the *in vitro* quantification of lactate in arterial, venous, or capillary whole blood.

The i-STAT lactate test is useful for (1) the diagnosis and treatment of lactic acidosis in conjunction with measurements of blood acid/base status, (2) monitoring tissue hypoxia and strenuous physical exertion, and (3) diagnosis of hyperlactatemia.

Contents

Each i-STAT cartridge contains one reference electrode (when potentiometric sensors are included in the cartridge configuration), sensors for the measurement of specific analytes, and a buffered aqueous calibrant solution that contains known concentrations of analytes and preservatives. For cartridges that contain a sensor for the measurement of lactate, a list of reactive ingredients is indicated below:

Reactive Ingredient	Biological Source	Minimum Quantity
Lactate	N/A	1.8 mmol/L
Lactate Oxidase	*Aerococcus viridans*	0.001 IU

Metrological Traceability

The i-STAT System test for lactate measures L-lactate amount-of-substance concentration in the plasma fraction of arterial, venous, or capillary whole blood (dimension mmol L^{-1}) for *in vitro* diagnostic use. Presently, no international conventional reference measurement procedure or international conventional calibrator for lactate is available. Lactate values assigned to i-STAT's controls and calibration verification materials are traceable to i-STAT's working calibrator prepared from sodium L-lactate (Sigma-Aldrich

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Fluka, >99 % purity). i-STAT System controls and calibration verification materials are validated for use only with the i-STAT System and assigned values may not be commutable with other methods. Further information regarding metrological traceability is available from Abbott Point of Care Inc..

Expected Values

Test/Abbreviation	Units*	Reportable Range	Reference[2] Range	
			(arterial)	(venous)
Lactate/Lac	mmol/L	0.30 – 20.00	0.36 – 1.25	0.90 – 1.70
	mg/dL	2.7 – 180.2	3.2 – 11.3	8.1 – 15.3

To convert a lactate result from mmol/L to mg/dL, multiply the mmol/L value by 9.01.

The i-STAT reference ranges for whole blood listed above are similar to reference ranges derived from serum or plasma measurements with standard laboratory methods.

The reference range shown above is intended to be used as a guide for the interpretation of results. Since reference ranges may vary with demographic factors such as age, gender and heritage, it is recommended that reference ranges be determined for the population being tested.

* The i-STAT System can be configured with the preferred units.

Clinical Significance

Elevated levels of lactate are mainly found in conditions of hypoxia such as shock, hypovolumia, and left ventricular failure; in conditions associated with diseases such as diabetes mellitus, neoplasia, and liver disease; and in conditions associated with drugs or toxins such as ethanol, methanol, or salicylates.[2]

Hyperlactatemia is an indicator commonly used to detect tissue hypoperfusion, particularly in the case of sepsis,[3-5] but also in trauma[6-8] and surgical[9-11] settings.

Performance Characteristics

The typical performance data summarized below was collected in health care facilities by health care professionals trained in the use of the i-STAT System and comparative methods.

Precision data were collected using CLSI guideline EP5-A[12]. Duplicates of each level of control were tested on three lots of cartridges over 20 days for a total of 120 replicates.

Method comparison data were collected using CLSI guideline EP9-A[13]. Venous blood samples, collected in sodium heparin Vacutainer® tubes, and arterial blood samples, collected in blood gas syringes, were analyzed in duplicate on the i-STAT System. In the plasma study, a portion of each specimen was centrifuged, and the separated plasma was analyzed on the comparative method.

Deming regression analysis[14] was performed on the first replicate of each sample. In the method comparison table, n is the number of specimens in the data set, Sxx and Syy refer to the estimates of imprecision based on the duplicates of the comparative and the i-STAT methods respectively, Sy.x is the standard error of the estimate, and r is the correlation coefficient.*

*The usual warning relating to the use of regression analysis is summarized here as a reminder: For any analyte, "if the data is collected over a narrow range, the estimate of the regression parameters are relatively imprecise and may be biased. Therefore, predictions made from these estimates may be invalid".[12] The correlation coefficient, r, can be used as a guide to assess the adequacy of the comparative method range in overcoming this problem. As a guide, the range of data can be considered adequate if r>0.975.

Precision Data (mmol/L)	Aqueous Control	n	Mean	SD	%CV
	Level 1	120	6.35	0.08	1.21
	Level 3	120	0.81	0.03	3.27

Method Comparison (mmol/L)	Radiometer ABL 725 (whole blood vs. whole blood)	Hitachi 917 (i-STAT whole blood vs. Hitachi plasma)
n	47	47
Sxx	0.123	0.084
Syy	0.136	0.079
Slope	1.02	1.06
Int't	0.12	-0.32
Sy.x	0.18	0.17
Xmin	0.80	1.77
Xmax	14.20	14.24
r	0.998	0.997

Factors Affecting Results*

Special collection procedures are necessary to prevent changes in lactate both during and after the blood is drawn. For steady state lactate concentrations, patients should be at rest for 2 hours and fasting. Venous samples should be obtained without the use of a tourniquet or immediately after the tourniquet is applied. Both venous and arterial samples may be collected into heparinized syringes.

Samples for lactate should be analyzed immediately on drawing as lactate increases by as much as 70% within 30 minutes at 25 °C as a result of glycolysis.[2]

Interference studies were based on CLSI guideline EP7-A2.[15] Test concentrations used were as per the CLSI guideline unless otherwise indicated.

When added to a plasma pool the following substances (at the concentrations indicated) were found to interfere with the i-STAT lactate assay:

Substance	Test Concentration (mmol/L)	Interference
Bromide	37.5	Use another method. See Note below
Glycolic Acid	10.0 [16]	Increased i-STAT lactate results. Use another method.
Hydroxyurea	0.92	Increased i-STAT lactate results. Use another method.

The following substances are known not to significantly interfere with the i-STAT lactate assay at the stated test concentrations:

Substance	Test Concentration (mmol/L)
Acetaldehyde	0.045 [16]
Acetaminophen	1.32
Acetylcysteine	10.2
Ascorbate	0.34
Bromide (therapeutic)	2.5 [17,18,19]
Dopamine	0.006
Formaldehyde	0.133 [16]
β-Hydroxybuterate	6.0 [20]
Pyruvate	0.31
Salicylate	4.34
Uric Acid	1.4

<u>Notes:</u>

1) Hydroxyurea is a DNA synthesis inhibitor used in the treatment of various forms of cancer, sickle cell anemia, and HIV infection. This drug is used to treat malignancies including melanoma, metastatic ovarian cancer, and chronic myelogenous leukemia. It is also used in the treatment of polycythemia vera, thrombocythemia, and psoriasis. At typical doses ranging from 500 mg to 2 g/day, concentrations of hydroxyurea in patients' blood may be sustained at approximately 100 to 500 µmol/L. Higher concentrations may be observed soon after dosing or at higher therapeutic doses.

2) Glycolic acid is a product of ethylene glycol metabolism. Unexpected increased lactate concentrations caused by glycolic acid may be a clue to the possibility of ethylene glycol ingestion as the cause of an otherwise unknown high anion gap metabolic acidosis.[21,22] In a study of 35 patients who had ingested ethylene glycol, initial glycolic acid concentrations of 0 to 38 mmol/L corresponded to ethylene glycol levels of 0.97 - 130.6 mmol/L.[22]

3) Bromide has been tested at two levels; the CLSI recommended level and a therapeutic plasma concentration level of 2.5 mmol/L. The latter is the peak plasma concentration associated with halothane anesthesia, in which bromide is released. APOC has not identified a therapeutic condition that would lead to levels consistent with the CLSI recommended level. Bromide at a concentration of 37.5 mmol/L decreased i-STAT lactate results, while a therapeutic range of bromide (2.5 mmol/L) did not significantly interfere with i-STAT lactate results.

* It is possible that other interfering substances may be encountered. The degree of interference at concentrations other than those listed might not be predictable.

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Abbott Point of Care Inc.
100 and 200 Abbott Park Road
Abbott Park, IL 60064 • USA

EC | REP
EMERGO EUROPE
Molenstraat 15
2513 BH The Hague
The Netherlands

CE

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CELITE ACTIVATED CLOTTING TIME/ (CELITEACT)

The i-STAT® Celite® Activated Clotting Time test, CeliteACT, is a measure of the time required for complete activation of the coagulation cascade.[1]

In traditional ACT tests, coagulation is initiated by mixing a whole blood sample with a particulate activator, and complete activation is indicated when extensive or localized clots form as activated thrombin converts fibrinogen to fibrin. These clots are mechanically detected.

The i-STAT CeliteACT test is similar to traditional ACT tests except that the endpoint is indicated by the conversion of a thrombin substrate other than fibrinogen and an electrochemical sensor is used to indicate the event of this conversion. The substrate used in the electrogenic assay has an amide linkage that mimics the thrombin-cleaved amide linkage in fibrinogen.

The substrate is H-D-phenylalanyl-pipecolyl-arginine-p-amino-p-methoxydiphenylamine which has the structure:

$$\text{Phenylalanine - Pipecolic acid - Arginine -- NH - C}_6\text{H}_4\text{ - NH - C}_6\text{H}_4\text{ - OCH}_3$$

Thrombin cleaves the amide bond at the carboxy- terminus of the arginine residue (denoted by the two dashes) because the bond structurally resembles the thrombin-cleaved amide linkage in fibrinogen. The product of the thrombin-substrate reaction is the electrochemically inert tripeptide Phenylalanyl - Pipecolyl - Arginine and the electroactive compound NH_3^+ - C_6H_4 - NH - C_6H_4 - OCH_3 . The formation of the electroactive compound is detected amperometrically, and the time of detection is measured in seconds. The test reports the Activated Clotting Time (ACT) as a whole blood time (WBT) in seconds.

The i-STAT CeliteACT test is calibrated to match the Hemochron Celite FTCA510 using prewarmed tubes. However, users of the i-STAT®1 analyzer may choose to customize their individual i-STAT locations to report ACT results as calibrated against the Hemochron Celite ACT using non-prewarmed (ambient) temperature tubes. This customization affects the Patient path only, and will not be applied to the Control or the Proficiency Testing pathway.

The customization in effect (prewarm or non-prewarm calibration mode) is identified on the analyzer screen as PREWRM or NONWRM, respectively. Please note that different locations within a given hospital may utilize different customization profiles. Prior to patient sample testing, ensure the appropriate calibration mode is employed. For a comprehensive discussion of this customization feature, please see the Technical Bulletin entitled "ACT Test Result Calibration Options: PREWARMED vs. NON-PREWARMED Result Calibration Modes for the i-STAT®1 Analyzer".

If results appear inconsistent with the clinical assessment, the patient sample should be re-tested using another cartridge.

Intended Use

The i-STAT Celite Activated Clotting Time (CeliteACT) test is an *in vitro* diagnostic test that uses fresh, whole blood, and is useful for monitoring patients receiving heparin for treatment of pulmonary embolism or venous thrombosis, and for monitoring anticoagulation therapy in patients undergoing medical procedures such as catheterization, cardiac surgery, surgery, organ transplant, and dialysis.

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Contents

Each i-STAT ^{Celite}ACT cartridge provides a sample collection chamber, sensors to detect the coagulation endpoint, and dry reagents necessary to initiate and allow coagulation. Stabilizers and reagents are coated on a section of the sensor channel and include the following reactive ingredients:

Reactive Ingredient	Minimum Quantity
Diatomaceous Earth	14.4 µg
Thrombin Substrate	0.36 µg

Metrological Traceability

The i-STAT System test for Celite Activated Clotting Time measures the time interval required for complete activation, by Celite®, of the coagulation cascade in arterial or venous whole blood (dimension seconds) for *in vitro* monitoring of moderate- and high-level heparin therapy. Presently, no international conventional reference measurement procedure or international conventional calibrator for ^{Celite}ACT is available. ^{Celite}ACT values assigned to i-STAT's controls are traceable to i-STAT's selected reference measurement procedure, which employs diatomaceous earth (Celite) activated glass reagent tubes, an automated timer and traditional viscometric clot detection and is run under specified temperature and sample conditions. i-STAT System controls are validated for use only with the i-STAT System and assigned values may not be commutable with other methods. Further information regarding metrological traceability is available from Abbott Point of Care Inc..

Expected Values

Test/Abbreviation	Units	Reportable Range	Reference Range (PREWRM)	Reference Range (NONWRM)
Activated Clotting Time/ACT	seconds	50 - 1000*	74 - 125	84 - 139

* The range from 80 - 1000 seconds has been verified through method comparison studies.

Clinical Significance

The ACT is primarily used to monitor a patient's state of anticoagulation due to heparin that is administered during a medical or surgical procedure. It is commonly employed in cardiac catheterization, Percutaneous Transluminal Coronary Angioplasty (PTCA), renal dialysis, hemodialysis, and extra-corporeal circulation during bypass.

Performance Characteristics

The typical performance data summarized below was collected in health care facilities by health care professionals trained in the use of the i-STAT System and comparative methods. All data uses the PREWRM calibration, unless otherwise noted.

Precision data were collected at Abbott Point of Care Inc. and during clinical trials following a protocol recommended by i-STAT and using plasma control material. Similar results can be expected in future performance studies provided the same experimental design and data analysis procedures are followed.

Plasma Control	n	Mean	SD	%CV
Level 1	329	221 seconds	18 seconds	8.1
Level 2	438	456 seconds	22 seconds	4.8

Method comparison data were collected using a modification of the CLSI guideline EP9-A[2]. Venous or arterial blood samples were collected in plastic syringes and analyzed in duplicate on the i-STAT System and in duplicate using the comparative methods. All samples were analyzed immediately upon collection. The patient populations in the studies were those in which ACT is routinely used. This includes baseline, heparin-treated, and heparin-reversed samples from from patients undergoing cardiac catheterization and cardiac bypass.

Deming regression analysis[3] was performed on the first replicate of each sample. In the method comparison table, n is the number of specimens in the data set, Sxx and Syy refer to estimates of the imprecision based on the duplicates of the comparative and i-STAT methods respectively, $Sy.x$ is the standard error of the estimate, and r is the correlation coefficient.

Method comparisons will vary from site to site due to differences in the sample handling, reagent and instrument systems in use, and other site-specific variables.

Cath Lab	Medtronic HR-ACT	Hemochron CA510/FT CA510
n	270	418
Sxx	10.1	19.7
Syy	10.7	13.5
Slope	1.15	0.86
Int't	-30	-3
Sy.x	32.5	22.5
Xmin	73	63
Xmax	523	763
r	0.848	0.903

CVOR	Hemchron CA510/FT CA510		
	Site 1	Site 2	Site 3
n	35	30	24
Sxx	15.8	34.2	24.4
Syy	13.0	11.5	20.8
Slope	0.85	1.10	1.19
Int't	4	-52	-73
Sy.x	43.8	17.4	62.1
Xmin	118	94	125
Xmax	671	735	767
r	0.912	0.952	0.891

Factors Affecting Results*

*It is possible that other interfering substances may be encountered. These results are representative and your results may differ somewhat due to test-to-test variation. The degree of interference at concentrations other than those listed might not be predictable.

Heparin sensitivity was demonstrated using whole blood samples to which varying concentrations of heparin were added *in vitro*.

The five graphs below each indicate the response of a different donor with respect to heparin concentration:

Heparin linearity, Donor 1

Heparin linearity, Donor 2

Heparin linearity, Donor 3

Heparin linearity, Donor 4

Heparin linearity, Donor 5
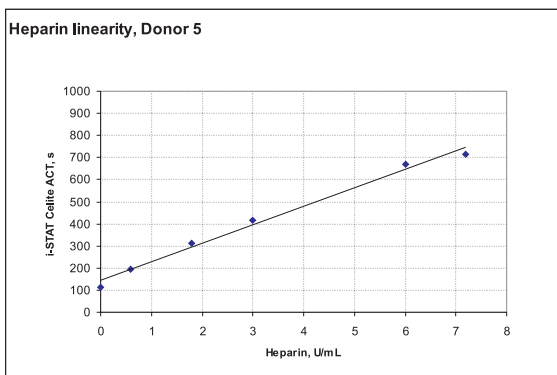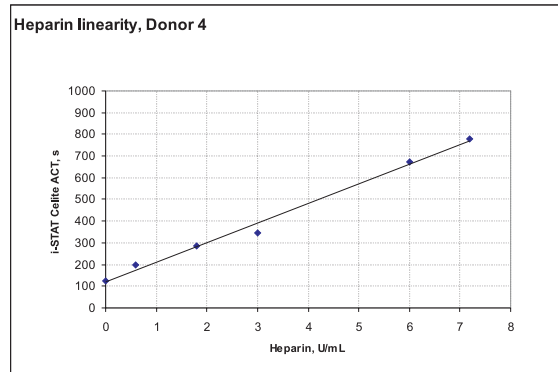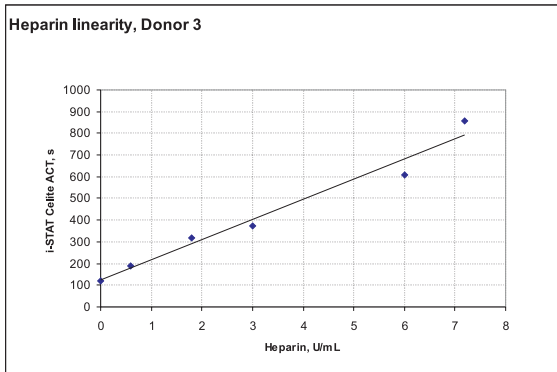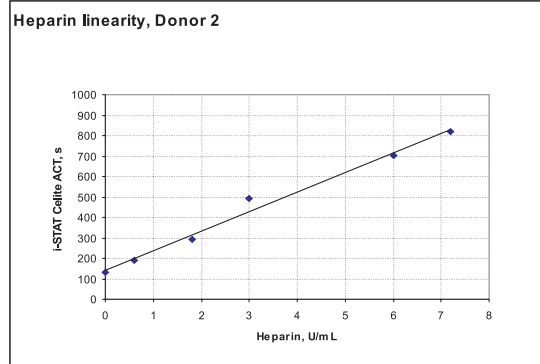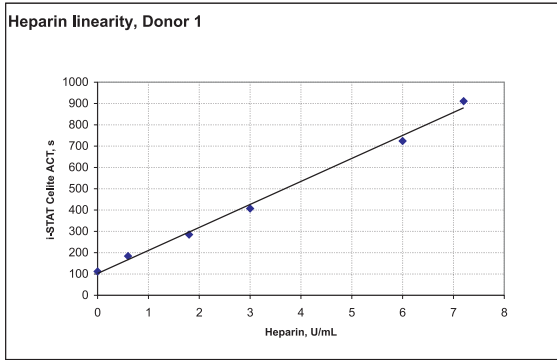
The graphs below indicate the response of the same five donors with respect to the ACT result on the Medtronic HR-ACT and the Hemochron Celite FTCA 510.

Method Comparison: i-STAT Celite ACT and Hemochron FTCA510

Method Comparison: i-STAT Celite ACT and Medtronic HR-ACT
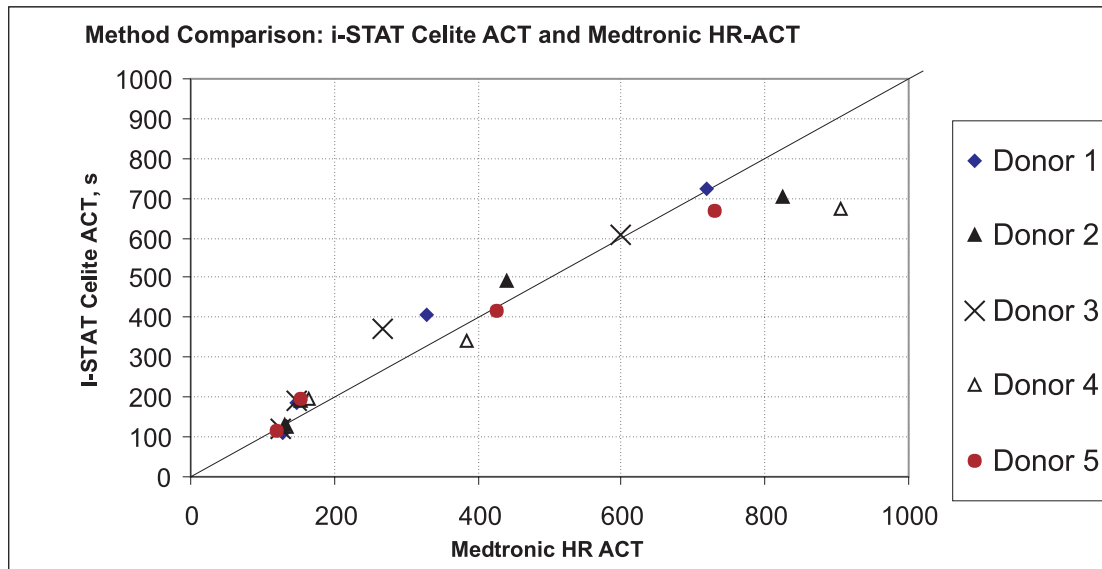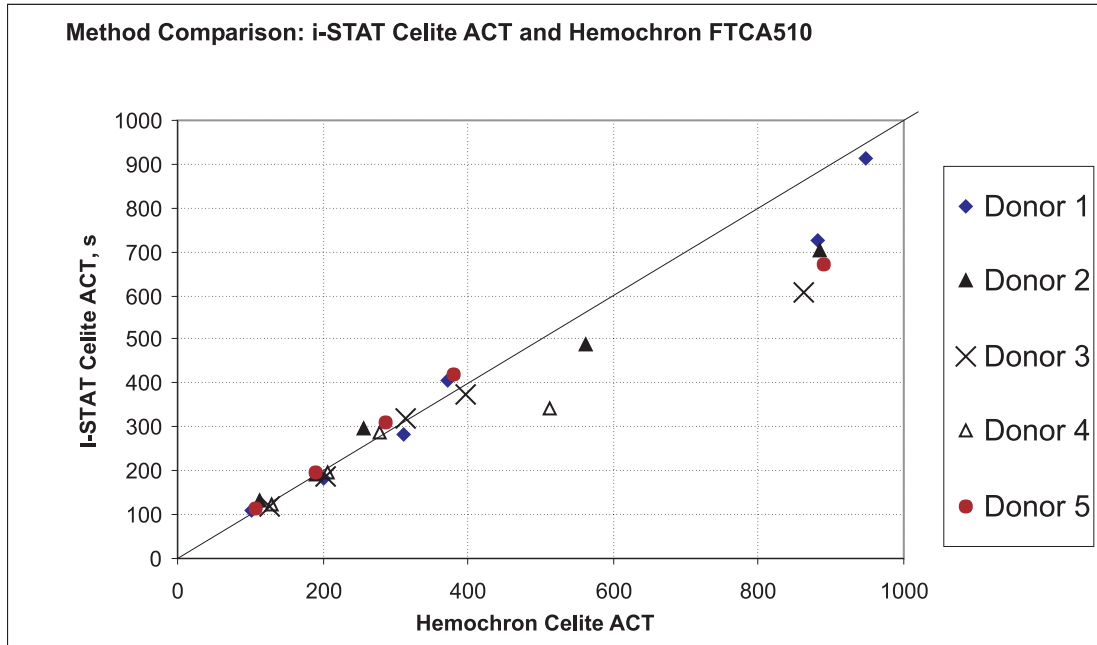
Performance of the i-STAT Celite ACT at lower levels of heparin is shown below with two "Low Range" ACT methods included for comparison:

Method Comparison: I-STAT Celite ACT and Medtronic LR-ACT

Method Comparison: i-STAT Celite ACT and Hemochron P214/P215
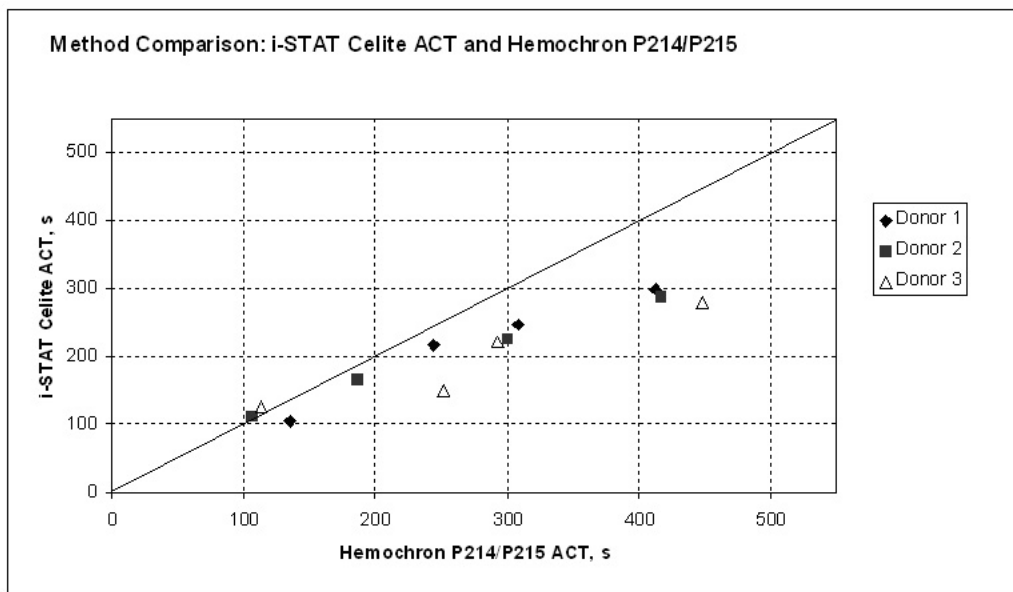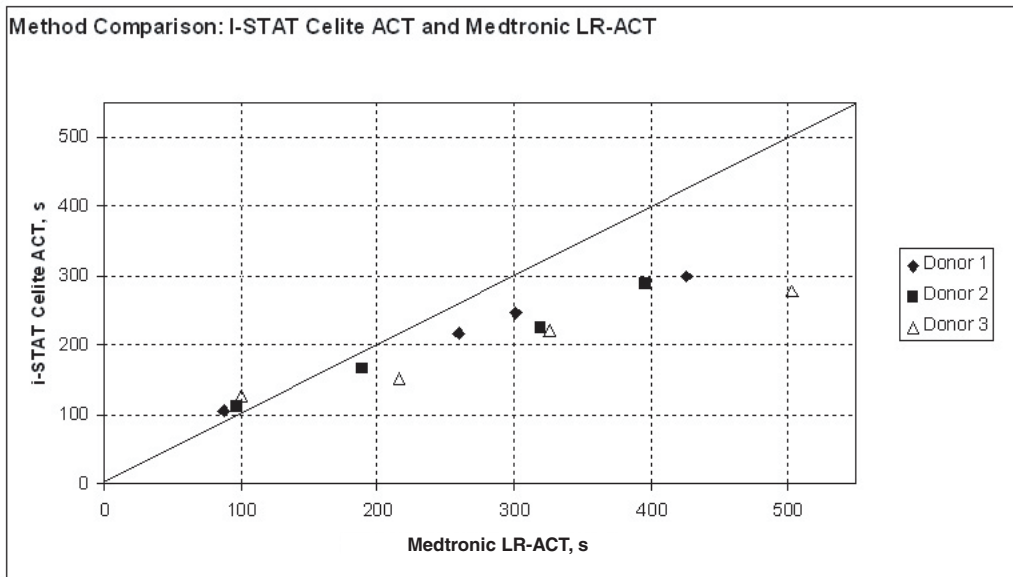
Test Limitations

The i-STAT Celite ACT test is to be used with fresh venous or arterial whole blood samples. The presence of exogenously added heparin, citrate, oxalate, or EDTA will interfere with test results. Poor technique in sample collection may also compromise the results. Samples drawn from insufficiently flushed catheters or from traumatic venipunctures may be contaminated with interfering substances. Samples should be collected into plastic syringes or tubes. Collection into glass may prematurely activate coagulation resulting in accelerated clotting times.

The i-STAT ACT test uses Celite brand diatomaceous earth as the activator of the intrinsic pathway. The result may, therefore, be prolonged in the presence of aprotinin.[4] **The test is not recommended for use with patients receiving aprotinin.**

The analyzer should remain on a level surface with the display facing up during testing. If the analyzer is not level, the ACT result may be affected by more than 10%. A level surface includes running the handheld in the downloader/recharger.

Hemodilution may affect test results.

Platelet dysfunction, hereditary or acquired, may affect the results of this test. This includes the administration of pharmacological compounds known as platelet inhibitors which affect platelet function. Factor deficiencies, dysprothrombinemias, other coagulopathies, and other pharmacological compounds may also affect the results of this test.

The i-STAT ACT test is not affected by hematocrit in the range of 20 - 70%, fibrinogen concentration in the range from 100 - 500 mg/dL, or sample temperature from 15 - 37°C.

Specimen Collection and Preparation

The i-STAT Celite ACT test can be performed using venous or arterial samples.

Venipunctures and Arterial Punctures

- Collection technique resulting in good blood flow must be used.
- The sample for testing should be drawn into a **plastic collection device** (either a plastic syringe or plastic evacuated tube).
- The collection device **cannot contain anticoagulants** such as heparin, EDTA, oxalate, or citrate.
- The collection device cannot contain clot activators or serum separators.
- The sample should be immediately dispensed into the sample well of a cartridge.
- If a second measurement is required, a fresh sample must be obtained.

Note: Some experts recommend drawing and discarding a sample of at least 1 mL prior to drawing sample for coagulation testing.[5]

Indwelling line

- Fluid drip through the line must be discontinued.
- If blood must be drawn from an indwelling line, possible heparin contamination and specimen dilution should be considered. The line should be flushed with 5 mL of saline and the first 5 mL of blood or six dead space volumes should be discarded.
- Withdraw the sample for testing into a fresh **plastic** syringe.
- The collection syringe **cannot contain anticoagulants** such as heparin, EDTA, oxalate, or citrate.
- The sample should be immediately dispensed into the sample well of a cartridge.
- If a second measurement is needed, draw a fresh sample.

Extracorporeal line

- Flush the extracorporeal blood access line by withdrawing 5 mL of blood into a syringe and discard the syringe.
- Withdraw the sample for testing into a fresh **plastic** syringe.
- The collection syringe **cannot contain anticoagulants** such as heparin, EDTA, oxalate, or citrate.
- The sample should be immediately dispensed into the sample well of a cartridge.
- If a second measurement is needed, draw a fresh sample.

References

1. Hattersly, P. Activated coagulation time of whole blood. Journal of the American Medical Association 136:436-440, 1966.

2. CLSI. *Method Comparison and Bias Estimation Using Patient Samples*; Approved Guideline. CLSI document EP9-A (ISBN 1-56238-283-7). CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087, 1995.

3. P.J. Cornbleet and N. Gochman, "Incorrect Least-Squares Regression Coefficients in Method Comparison Analysis," Clinical Chemistry 25:3, 432 (1979).

4. Wang, JS; Lin, CY; Hung, WT; Thisted, RA; Carp, RB. In vitro effects of aprotinin on activated clotting time measured with different activators. Journal of Thoracic Cardiovascular Surgery 104(4):1135-40, 1992.

5. Corriveau, Donna: Fritsma, George (ed.): Hemostasis and Thrombosis in the Clinical Laboratory. Ed, J.B. Lippinncott Company, Philadelphia, 1988, pp 70-71.

Abbott Point of Care Inc.
Abbott Park, IL 60064 • USA

EC | REP

Emergo Europe
Molenstraat 15
2513 BH, The Hague
The Netherlands
Tel: (31)70 345 8570
Fax: (31)70 346 7299

CE   IVD

KAOLIN ACTIVATED CLOTTING TIME/ (^KAOLIN^ACT)

The i-STAT® Kaolin Activated Clotting Time test, ^Kaolin^ACT, is a measure of the time required for complete activation of the coagulation cascade.[1]

In traditional ACT tests, coagulation is initiated by mixing a whole blood sample with a particulate activator, and complete activation is indicated when extensive or localized clots form as activated thrombin converts fibrinogen to fibrin. These clots are mechanically detected.

The i-STAT ^Kaolin^ACT test is similar to traditional ACT tests except that the endpoint is indicated by the conversion of a thrombin substrate other than fibrinogen and an electrochemical sensor is used to indicate the event of this conversion. The substrate used in the electrogenic assay has an amide linkage that mimics the thrombin-cleaved amide linkage in fibrinogen.

The substrate is H-D-phenylalanyl-pipecolyl-arginine-*p*-amino-*p*-methoxydiphenylamine which has the structure:

$$\text{Phenylalanine - Pipecolic acid - Arginine -- NH - C}_6\text{H}_4\text{ - NH - C}_6\text{H}_4\text{ - OCH}_3$$

Thrombin cleaves the amide bond at the carboxy- terminus of the arginine residue (denoted by the two dashes) because the bond structurally resembles the thrombin-cleaved amide linkage in fibrinogen. The product of the thrombin-substrate reaction is the electrochemically inert tripeptide Phenylalanyl - Pipecolyl - Arginine and the electroactive compound $NH_3^+ - C_6H_4 - NH - C_6H_4 - OCH_3$. The formation of the electroactive compound is detected amperometrically, and the time of detection is measured in seconds. The test reports the Activated Clotting Time (ACT) in seconds.

The i-STAT ^Kaolin^ACT test is calibrated to match the Hemochron Celite FTCA510 using prewarmed reagent tubes. However, users of the i-STAT®1 analyzer may choose to customize their individual i-STAT locations to report ACT results as calibrated against the Hemochron Celite ACT using non-prewarmed (ambient temperature) tubes. This customization affects the Patient path only, and will not be applied to the Control or the Proficiency Testing pathway.

The customization in effect (prewarm or non-prewarm calibration mode) is identified on the analyzer screen as PREWRM or NONWRM, respectively. Please note that different locations within a given hospital may utilize different customization profiles. Prior to patient sample testing, ensure the appropriate calibration mode is employed. For a comprehensive discussion of this customization feature, please see the Technical Bulletin entitled "ACT Test Result Calibration Options: PREWARMED vs. NON-PREWARMED Result Calibration Modes for the i-STAT®1 Analyzer".

If results appear inconsistent with the clinical assessment, the patient sample should be re-tested using another cartridge.

Intended Use

The i-STAT Kaolin Activated Clotting Time (^Kaolin^ACT) test is an *in vitro* diagnostic test that uses fresh, whole blood, and is used to monitor high-dose heparin anticoagulation frequently associated with cardiovascular surgery.

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Contents

Each i-STAT KaolinACT cartridge provides a sample collection chamber, sensors to detect the coagulation endpoint, and dry reagents necessary to initiate and allow coagulation. Stabilizers and reagents are coated on a section of the sensor channel and include the following reactive ingredients:

Reactive Ingredient	Minimum Quantity
Kaolin	23.4 µg
Thrombin Substrate	0.09 µg

Metrological Traceability

The i-STAT System test for Kaolin Activated Clotting Time measures the time interval required for complete activation, by kaolin, of the coagulation cascade in arterial or venous whole blood (dimension seconds) for *in vitro* monitoring of high-level heparin therapy. Presently, no international conventional reference measurement procedure or international conventional calibrator for KaolinACT is available. KaolinACT values assigned to i-STAT's controls are traceable to i-STAT's selected reference measurement procedure, which employs Celite activated glass reagent tubes, an automated timer and traditional viscometric clot detection and is run under specified temperature and sample conditions. i-STAT System controls are validated for use only with the i-STAT System and assigned values may not be commutable with other methods. Further information regarding metrological traceability is available from Abbott Point of Care Inc..

Expected Values

Test/Abbreviation	Units	Reportable Range	Reference Range (PREWRM)	Reference Range (NONWRM)
Activated Clotting Time/ACT	seconds	50 - 1000*	74 - 137	82- 152

* The range from 77 - 1000 seconds (PREWRM mode) has been verified through method comparison studies.

Clinical Significance

The ACT is primarily used to monitor a patient's state of anticoagulation due to heparin that is administered during a medical or surgical procedure. It is commonly employed in cardiac catheterization, Percutaneous Transluminal Coronary Angioplasty (PTCA), renal dialysis, hemodialysis, and extra-corporeal circulation during bypass.

Performance Characteristics

The typical performance data summarized below was collected in health care facilities by health care professionals trained in the use of the i-STAT System and comparative methods. All data uses the PREWRM calibration, unless otherwise noted.

Precision data were collected at i-STAT and during clinical trials following a protocol recommended by i-STAT and using plasma control material. Similar results can be expected in future performance studies provided the same experimental design and data analysis procedures are followed.

Plasma Control	n	Mean	SD	%CV
Level 1	119	169 seconds	4 seconds	2.0
Level 2	113	409 seconds	21 seconds	5.2

Method comparison data were collected using a modification of the CLSI guideline EP9-A[2]. Venous or arterial blood samples were collected in plastic syringes and analyzed in duplicate on the i-STAT System and in duplicate using the comparative methods. All samples were analyzed immediately upon collection. The patient populations in the studies were those in which ACT is routinely used and included both aprotinin and non-aprotinin receiving patients. All were undergoing cardiac surgery. Sample types included baseline, heparin-treated, and heparin-reversed samples.

Deming regression analysis[3] was performed on the first replicate of each sample. In the method comparison table, *n* is the number of specimens in the data set, *Sxx* and *Syy* refer to estimates of the imprecision based on the duplicates of the comparative and i-STAT methods respectively, *Sy.x* is the standard error of the estimate, and *r* is the correlation coefficient.

Method comparisons will vary from site to site due to differences in the sample handling, reagent and instrument systems in use, and other site-specific variables.

	Hemochron FTK-ACT		
CVOR	**Site 1**	**Site 2**	**Site 3**
n	104	118	106
Sxx	9.1%	6.8%	7.6%
Syy	3.6%	4.0%	3.6%
Slope	0.96	1.05	0.96
Intercept	-12	-38	-39
Xmin	68	111	81
Xmax	1286	1310	1102
r	0.906	0.940	0.971

Factors Affecting Results*

The i-STAT ^Kaolin^ACT test is not significantly prolonged in the presence of aprotinin (Trasylol).

*It is possible that other interfering substances may be encountered. These results are representative and your results may differ somewhat due to test-to-test variation. The degree of interference at concentrations other than those listed might not be predictable.

Heparin sensitivity was demonstrated using whole blood samples to which varying concentrations of heparin were added *in vitro*.

The following three graphs below each indicate the response of a different donor with respect to heparin concentration:

Heparin Linearity, Donor 1

Heparin Linearity, Donor 2
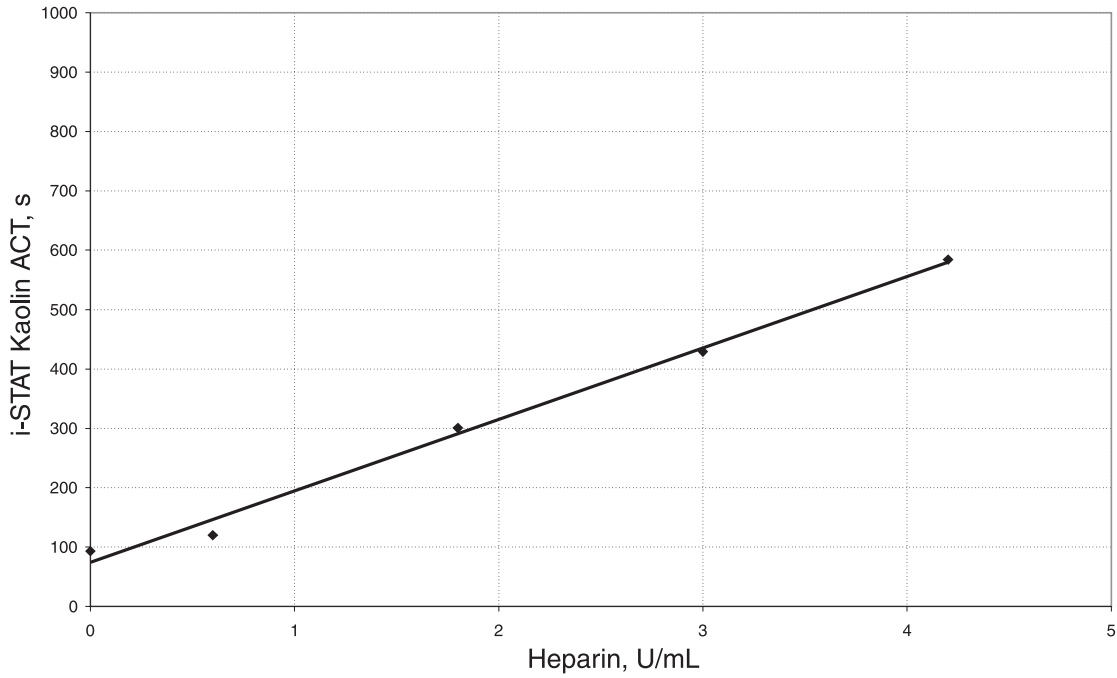
Heparin Linearity, Donor 3
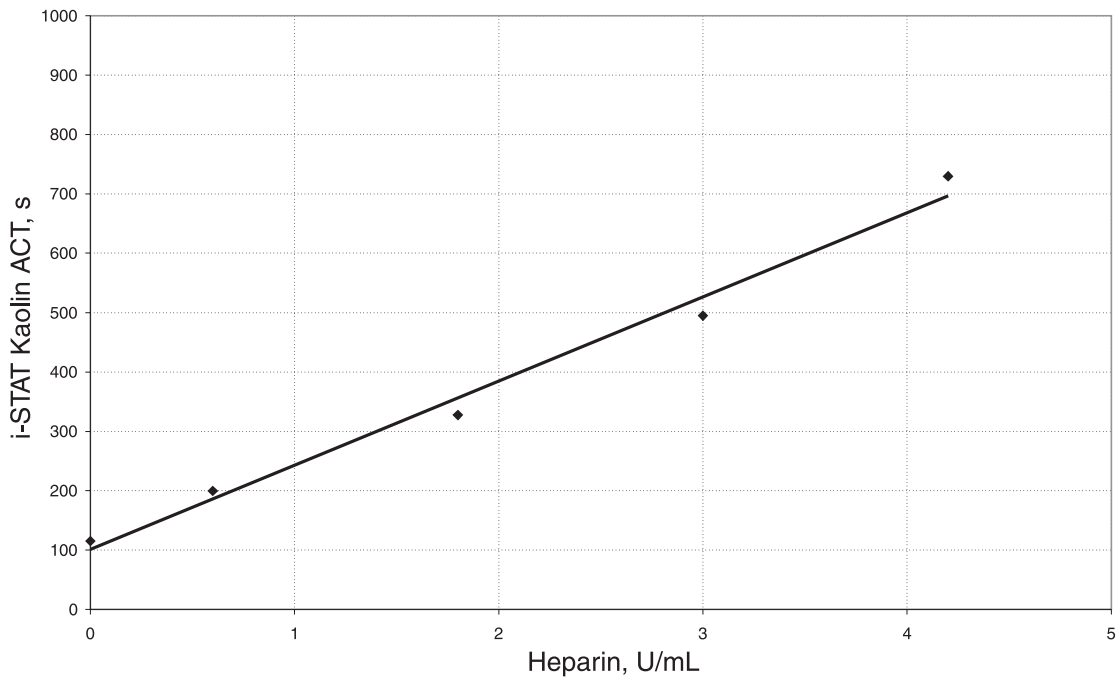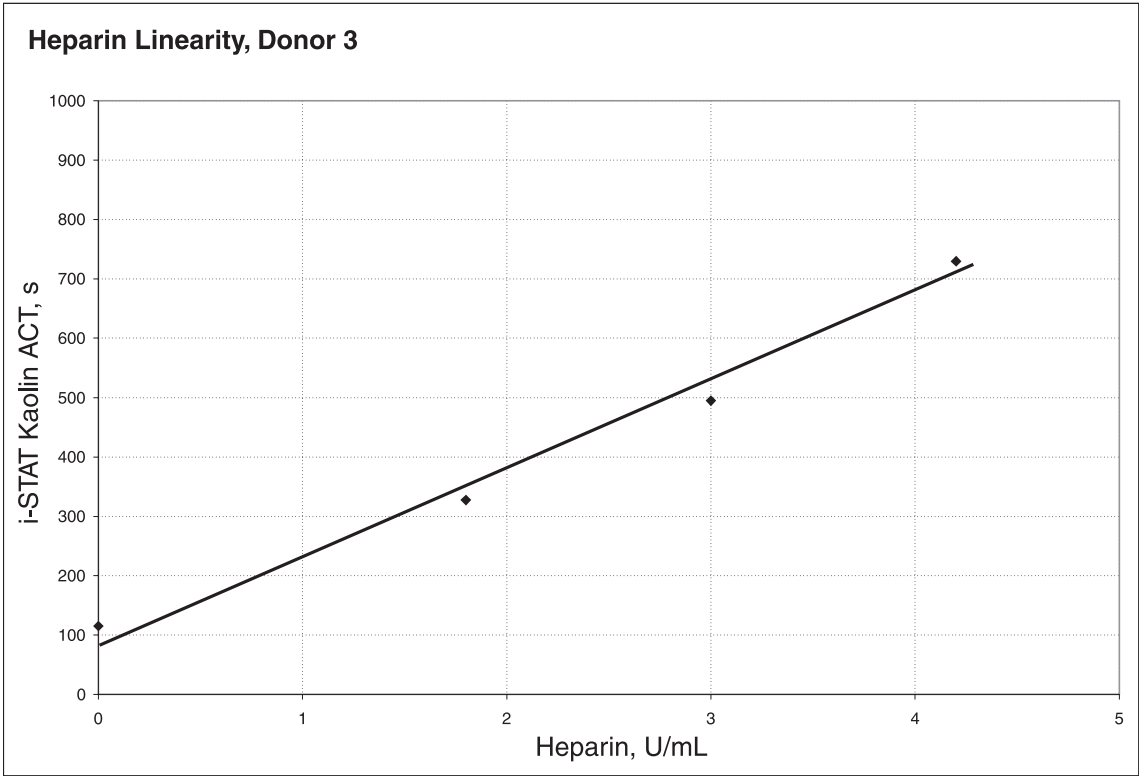
The following two graphs indicate the response of the same three donors with respect to the ACT result on the Medtronic HR-ACT and the Hemochron Kaolin FTK-ACT.

Method Comparison i-STAT Kaolin ACT and Hemochron FTK-ACT

Method Comparison i-STAT Kaolin ACT and Medtronic HR-ACT
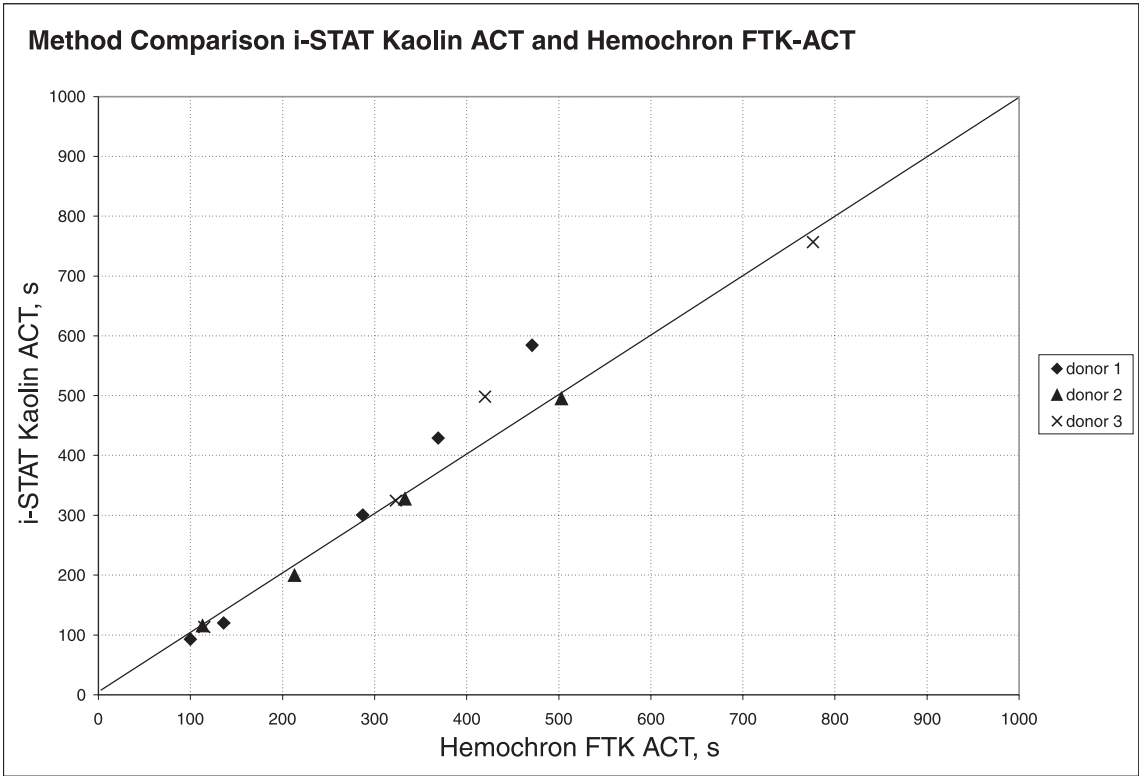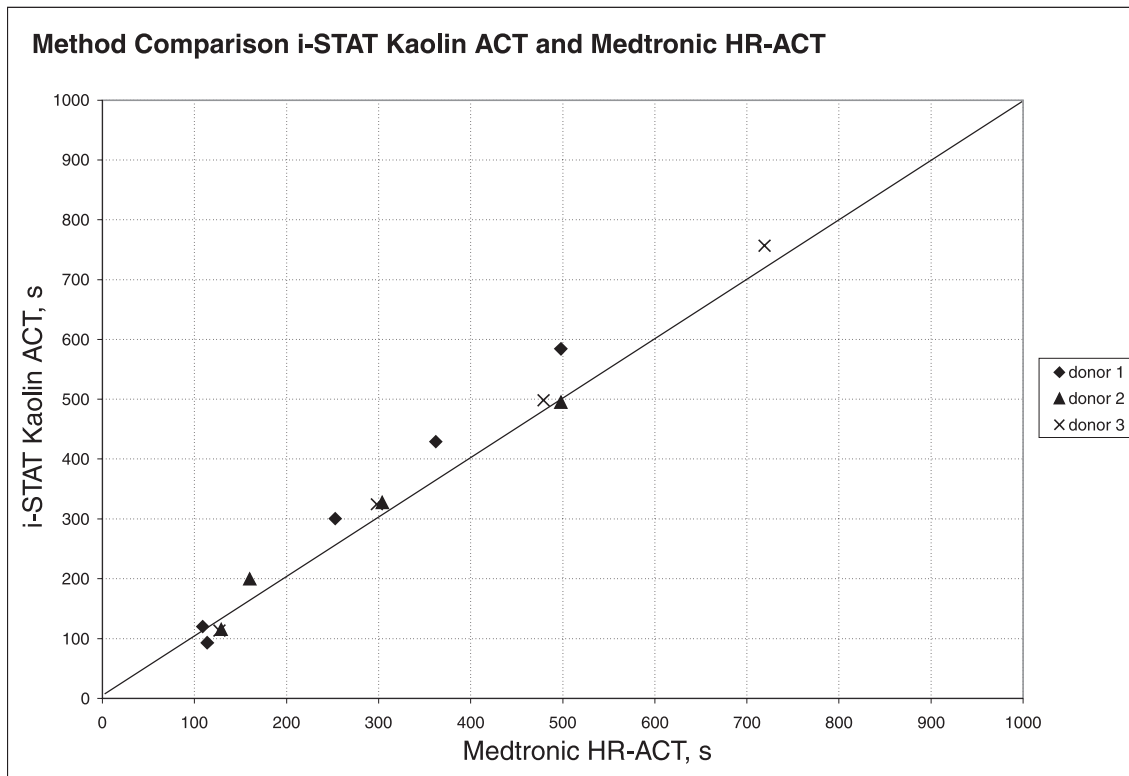
Test Limitations

The i-STAT ^Kaolin^ACT test is to be used with fresh venous or arterial whole blood samples. The presence of exogenously added heparin, citrate, oxalate, or EDTA will interfere with test results. Poor technique in sample collection may also compromise the results. Samples drawn from insufficiently flushed catheters or from traumatic venipunctures may be contaminated with interfering substances. Samples should be collected into plastic syringes or tubes. Collection into glass may prematurely activate coagulation resulting in accelerated clotting times.

The analyzer should remain on a level surface with the display facing up during testing. If the analyzer is not level, the ACT result may be affected by more than 10%. A level surface includes running the handheld in the downloader/recharger.

Hemodilution may affect test results.

Platelet dysfunction, hereditary or acquired, may affect the results of this test. This includes the administration of pharmacological compounds known as platelet inhibitors which affect platelet function. Factor deficiencies, dysprothrombinemias, other coagulopathies, and other pharmacological compounds may also affect the results of this test.

The i-STAT ACT test is not affected by fibrinogen concentration in the range from 100 - 500 mg/dL, or sample temperature from 15 - 37°C.

Specimen Collection and Preparation

The i-STAT ^Kaolin^ACT test can be performed using venous or arterial samples.

Venipunctures and Arterial Punctures

- Collection technique resulting in good blood flow must be used.
- The sample for testing should be drawn into a **plastic collection device** (either a plastic syringe or plastic evacuated tube).
- The collection device **cannot contain anticoagulants** such as heparin, EDTA, oxalate, or citrate.
- The collection device cannot contain clot activators or serum separators.
- The sample should be immediately dispensed into the sample well of a cartridge.
- If a second measurement is required, a fresh sample must be obtained.

Note: Some experts recommend drawing and discarding a sample of at least 1 mL prior to drawing sample for coagulation testing.[4]

Indwelling line

- Fluid drip through the line must be discontinued.
- If blood must be drawn from an indwelling line, possible heparin contamination and specimen dilution should be considered. The line should be flushed with 5 mL of saline and the first 5 mL of blood or six dead space volumes should be discarded.
- Withdraw the sample for testing into a fresh **plastic** syringe.
- The collection syringe **cannot contain anticoagulants** such as heparin, EDTA, oxalate, or citrate.
- The sample should be immediately dispensed into the sample well of a cartridge.
- If a second measurement is needed, draw a fresh sample.

Extracorporeal line

- Flush the extracorporeal blood access line by withdrawing 5 mL of blood into a syringe and discard the syringe.
- Withdraw the sample for testing into a fresh **plastic** syringe.
- The collection syringe **cannot contain anticoagulants** such as heparin, EDTA, oxalate, or citrate.
- The sample should be immediately dispensed into the sample well of a cartridge.
- If a second measurement is needed, draw a fresh sample.

References

1. Hattersly, P. Activated coagulation time of whole blood. Journal of the American Medical Association 136:436-440, 1966.

2. CLSI. *Method Comparison and Bias Estimation Using Patient Samples*; Approved Guideline. CLSI document EP9-A (ISBN 1-56238-283-7). CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087, 1995.

3. P.J. Cornbleet and N. Gochman, "Incorrect Least-Squares Regression Coefficients in Method Comparison Analysis," Clinical Chemistry 25:3, 432 (1979).

4. Corriveau, Donna: Fritsma, George (ed.): Hemostasis and Thrombosis in the Clinical Laboratory. Ed, J.B. Lippinncott Company, Philadelphia, 1988, pp 70-71.

Abbott Point of Care Inc.
Abbott Park, IL 60064 • USA

EC REP

Emergo Europe
Molenstraat 15
2513 BH, The Hague
The Netherlands
Tel: (31)70 345 8570
Fax: (31)70 346 7299

CE

IVD

PROTHROMBIN TIME/ (PT/INR)

The i-STAT® PT/INR test is a whole blood determination of the prothrombin time used for monitoring oral anticoagulant (Coumadin or warfarin) therapy. The test determines the time required for complete activation of the extrinsic pathway of the coagulation cascade when initiated (activated) with a thromboplastin.

In a prothrombin time test, coagulation is initiated by mixing the sample with tissue thromboplastin. In traditional prothrombin time tests, complete activation is indicated when activated thrombin converts fibrinogen to fibrin and extensive or localized clots are detected mechanically or optically. The i-STAT PT/INR test is similar except that the endpoint is indicated by the conversion of a thrombin substrate other than fibrinogen. An electrochemical sensor is used to detect this conversion.

The added thrombin substrate is H-D-phenylalanyl-pipecolyl-arginine-p-amino-p-methoxydiphenylamine, which has the structure:

$$Phenylalanine - Pipecolic\ acid - Arginine\ -- NH - C_6H_4 - NH - C_6H_4 - OCH_3$$

Thrombin cleaves the amide bond at the carboxy terminus of the arginine residue (denoted by the two dashes) because the bond structurally resembles the thrombin-cleaved amide linkage in fibrinogen. The product of the thrombin-substrate reaction is the electrochemically inert tripeptide Phenylalanyl - Pipecolyl - Arginine and the electroactive compound $NH_3^+ - C_6H_4 - NH - C_6H_4 - OCH_3$. A formation of the electroactive compound is detected amperometrically and the time of detection is measured.

The PT/INR test result is reported as an International Normalized Ratio (INR) and, optionally, in seconds. The INR is the recommended method of result reporting for monitoring of oral anticoagulant therapy.[1] A Mean Normal i-STAT prothrombin time (sec) and an ISI are determined following the WHO recommendations at a CAP-accredited facility. INR results are calculated using the following equation:

$$INR = \left\lceil \frac{Patient\ i\text{-}STAT\ prothrombin\ time\ (sec)}{Mean\ Normal\ i\text{-}STAT\ prothrombin\ time\ (sec)} \right\rceil^{ISI}$$

The optionally displayed units of seconds reflect traditional plasma PT times. The reported time is derived from the PT/INR result and the equation below using an ISI of 1.05 and a typical Mean Normal Plasma PT time of 12.0 seconds.

$$INR = \left\lceil \frac{Patient\ Plasma\ prothrombin\ time\ (sec)}{Mean\ Normal\ Plasma\ prothrombin\ time\ (sec)} \right\rceil^{ISI}$$

If results appear inconsistent with the clinical assessment, the patient sample should be recollected and retested using another cartridge.

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Intended Use

The i-STAT PT, a prothrombin time test, is useful for monitoring patients receiving oral anticoagulation therapy such as Coumadin or warfarin.

Contents

Each i-STAT PT/INR cartridge provides a sample collection chamber, sensors to detect the coagulation endpoint and dry reagents necessary to initiate and allow coagulation. Inert matrix components and reagents are coated on a section of the sensor channel and include the following reactive ingredients:

Reactive Ingredient	Biological Source	Minimum Quantity
Recombinant Tissue Thromboplastin	Human	0.18 mg
Heparinase I	*Flavobacterium heparinum*	0.018 IU
Thrombin Substrate	N/A	0.4 µg

Metrological Traceability

The i-STAT System test for Prothrombin Time (PT/INR) measures the International Normalized Ratio (dimensionless) expressing the relative time interval required for complete activation, by thromboplastin, of the coagulation cascade in capillary or venous whole blood for *in vitro* monitoring of oral anticoagulant (Coumadin or warfarin) therapy. PT/INR values assigned to i-STAT's controls are traceable to the World Health Organization (WHO) international reference measurement procedures and the International Reference Preparation recommended by the WHO.[2] i-STAT System controls are validated for use only with the i-STAT System and assigned values may not be commutable with other methods. Further information regarding metrological traceability is available from Abbott Point of Care Inc.

Expected Values

Test/Abbreviation	Units	Verified Clinical Range
Prothrombin Time/ (PT/INR)	INR	0.9 - 6.0*

*The performance characteristics of the i-STAT PT/INR measurement have not been established at INRs above 6.0.

Performance Characteristics

The typical performance data summarized below were collected in healthcare facilities by healthcare professionals trained in the use of the i-STAT System and comparative methods.

Imprecision

Initial studies were conducted to collect imprecision data for venous and capillary whole blood samples. Imprecision data for venous whole blood samples were collected in duplicate at two clinical sites. Imprecision data for capillary whole blood samples were collected in duplicate at one clinical site using a single capillary stick. The table below summarizes this data.

Statistic	Site 1 (venous)	Site 2 (venous)	Site 3 (capillary)
n	181	102	33
Mean (INR)	2.6	2.4	2.5
%CV	4.7%	4.0%	4.6%

The below imprecision data for lyophilized plasma control material were collected during studies at an Abbott Point of Care facility and during clinical trials. SD and %CV are typical of current performance. Current Value Assignment Sheets should be referenced for applicable plasma control mean data.

Plasma Control	Mean	SD	%CV
Level 1	1.1 (INR)	0.05	4.5%
Level 2	2.5 (INR)	0.17	6.9%

Reference Interval

In a study to determine a reference interval for PT/INR, venous samples from healthy volunteers were collected in plastic tubes, and whole blood was analyzed with one lot of cartridges on the i-STAT System. Capillary samples were obtained from the same volunteers using Softclick Pro (setting of 3) and analyzed on the same cartridge lot. Reference intervals for INR in venous and capillary samples were determined according to the CLSI Guideline C28-A2.[3] The data are summarized in the table below:

Statistic	Venous whole blood	Capillary whole blood
n	120	119
Mean (INR)	1.0	1.0
SD	0.1	0.1
Reference Range (INR)	0.8 - 1.2	0.8 - 1.2

Due to the many variables that may affect PT/INR results, each laboratory should establish its own reference interval.

Method Comparison

Method comparison data were collected at the Hemostasis Reference Laboratory (Hamilton, Ontario, Canada). Venous samples from outpatients undergoing routine oral anticoagulation therapy were collected in plastic tubes and analyzed in duplicate on multiple lots of cartridges on the i-STAT System; plasma from tubes containing a citrate anticoagulant were analyzed in duplicate on the comparative instruments using Dade® Innovin®, STA Neoplastine® CI Plus, and the HemosIL® RecombiPlasTin 2G® reagents.

Deming regression analysis[4] was performed on the first replicate of each sample. In the method comparison table below, n is the number of specimens in the data set, $Sy.x$ is the standard error of the estimate, and r is the correlation coefficient.

Method comparisons will vary from site to site due to differences in the sample handling, reagent and instrument systems in use, and other site-specific variables. A correlation study should be performed to establish the differences between the i-STAT PT/INR measurement and other methods used.

Statistic	i-STAT vs. Siemens Sysmex® CA-1500 and Dade® Innovin® reagent	i-STAT vs. STA Compact® and Neoplastine® CI Plus reagent	i-STAT vs. IL ACL 7000 and HemosIL® RecombiPlasTin 2G® reagent
n	78	78	69
Mean (INR)	2.1	2.1	2.2
Range (INR)	0.9 - 4.5	0.9 - 4.1	0.9 – 4.0
Sx (INR)	0.843	0.772	0.840
Slope	0.981	1.074	0.972
Intercept (INR)	0.084	-0.100	0.003
r	0.963	0.964	0.962
Sy.x	0.233	0.229	0.233

Siemens Sysmex® CA 1500 PT (INR)

STA Compact® PT (INR)
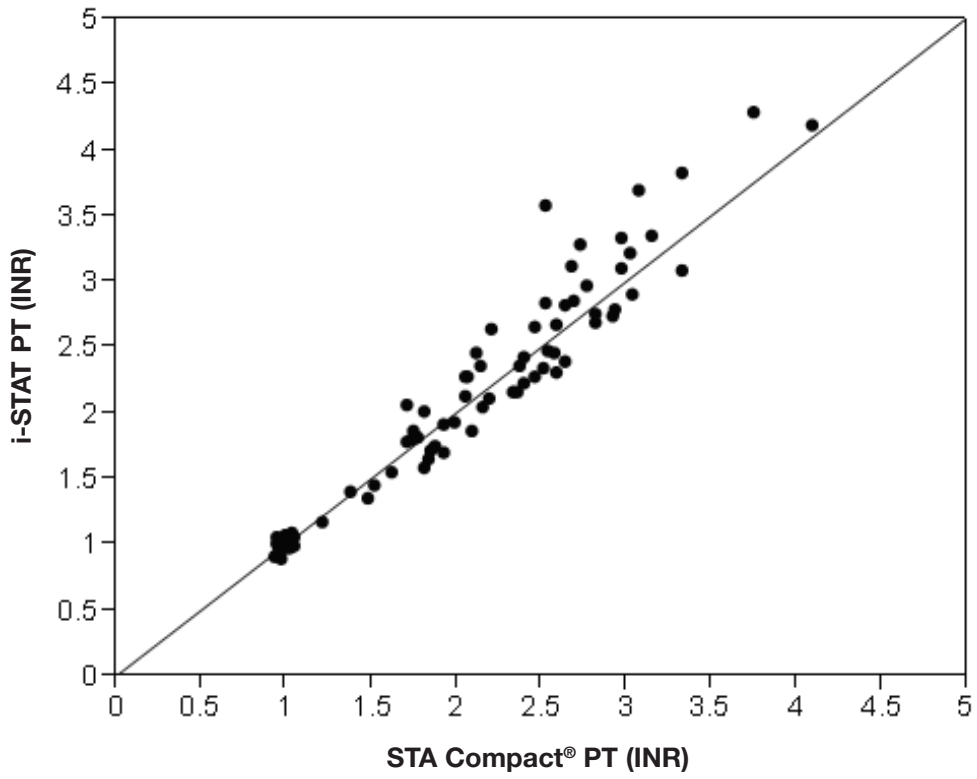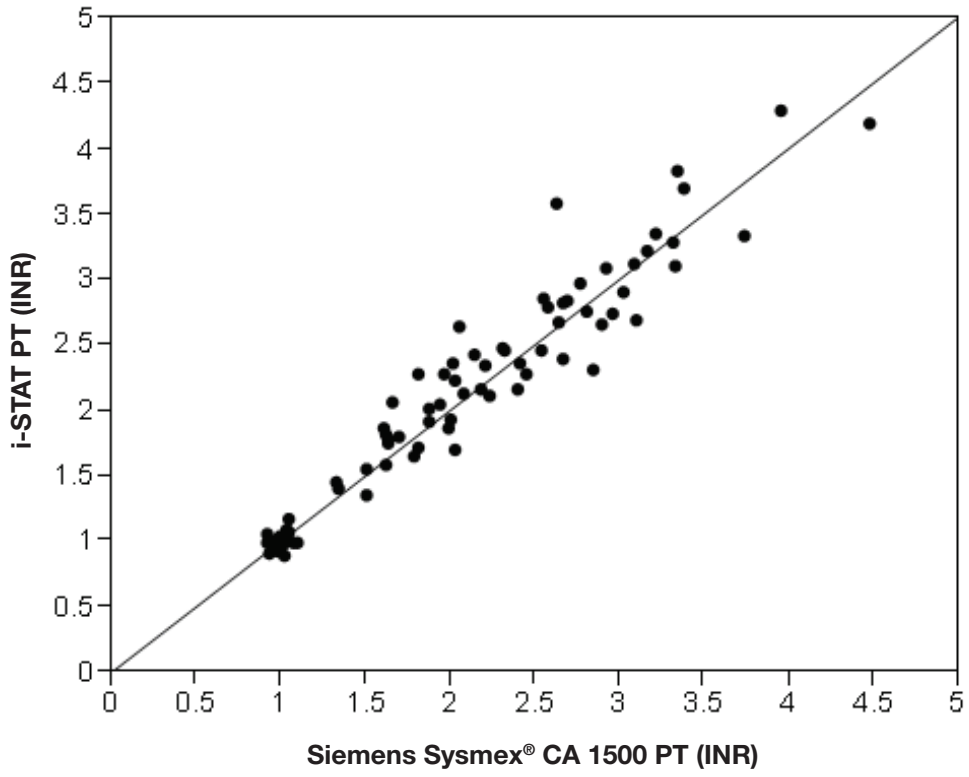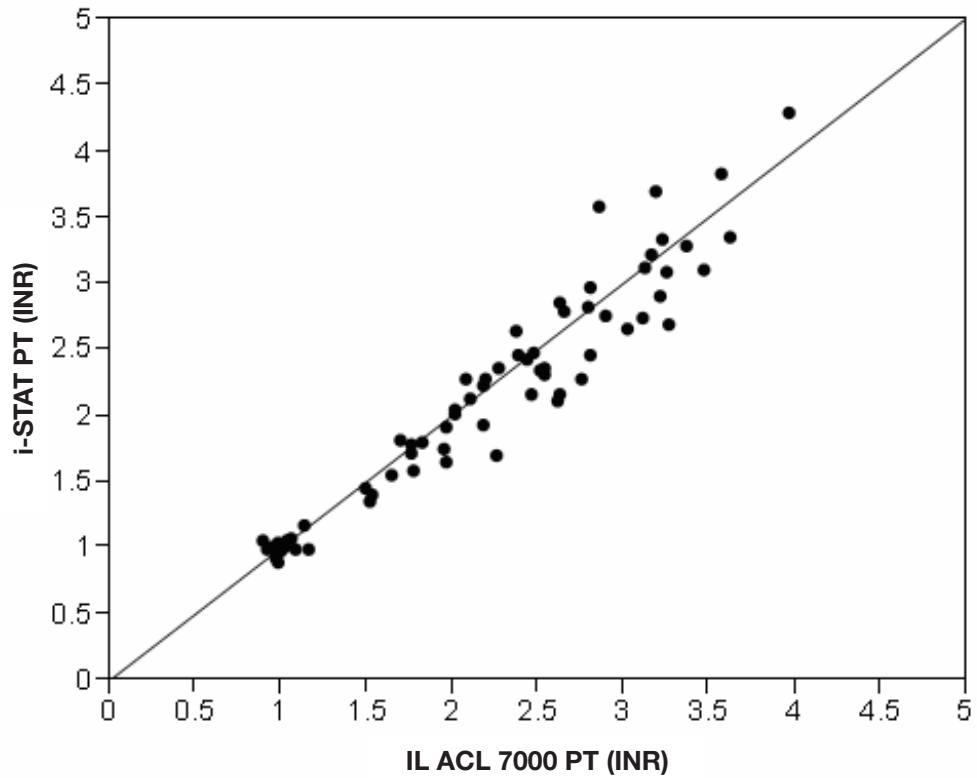
Data is presented below from one clinical site comparing data from capillary samples to data from venous samples analyzed on the i-STAT System.

Statistic	Capillary vs. Venous
n	39
Mean (INR)	2.4
Range (INR)	1.3 – 5.4
Sx (INR)	0.960
Slope	1.049
Intercept (INR)	-0.098
Sy.x	0.128
r	0.978
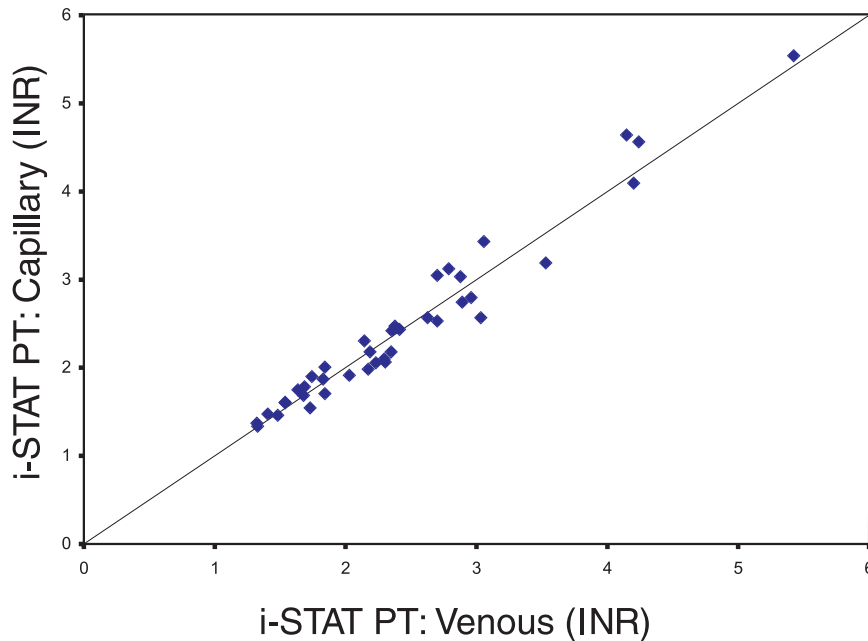
Factors Affecting Results

- The presence of exogenously added heparin, citrate, oxalate, or EDTA from blood collection devices will interfere with test results.

- Poor technique in sample collection may compromise the results. (See Specimen Collection and Preparation below.)

- Glass syringes or tubes may prematurely activate coagulation, resulting in accelerated clotting times and lower INRs. Venous samples must be collected into plastic syringes or tubes.

- PT/INR results may be affected by commonly administered drugs.

- Abbott Point of Care has not characterized the i-STAT PT/INR test with patients that have lupus anticoagulant antibodies. If the presence of lupus anticoagulant antibodies is known or suspected, consider using a prothrombin time laboratory assay using a reagent that is known to be insensitive to lupus anticoagulant antibodies or an alternate laboratory method.

Limitations of the i-STAT PT/INR Test

- The analyzer must remain on a level, vibration-free surface with the display facing up during testing. A level surface includes running the handheld in the downloader/recharger.

- The i-STAT PT/INR test is not affected by fibrinogen concentrations between 70 and 541 mg/dL. The i-STAT PT/INR electrogenic test methodology does not measure the physical clot and is not dependent on whether or not fibrinogen forms into an actual physical fibrin clot. As such, the i-STAT PT/INR test will not reflect the extension of coagulation time associated with the depletion of fibrinogen (e.g., consumptive coagulopathy), disseminated intravascular coagulation (DIC), or defibrination syndrome.

- The i-STAT PT/INR test is not affected by unfractionated heparin concentrations up to 1.0 U/mL.

- Hematocrits in the range of 24 – 54% PCV have been demonstrated not to affect results.

- Cubicin® (daptomycin for injection) has been found to cause a concentration-dependent false prolongation of prothrombin time (PT) and elevation of INR when using the i-STAT PT/INR test. It is recommended that for patients being treated with this antibiotic, an alternate method be used to evaluate PT/INR.

- The i-STAT PT/INR test may report a false prolongation of the prothrombin time (PT) and an elevation of the INR on samples contaminated with chlorhexidine gluconate.

- The i-STAT PT/INR test is not intended for evaluating individual factor deficiencies.

Specimen Collection and Preparation

Caution: The i-STAT PT/INR cartridge is designed to accept a sample between 20 and 45 microliters. A single drop of blood from either a finger puncture or as formed at the tip of a syringe will typically be within this range. If a larger volume is delivered to the sample well, use caution when closing the cartridge as excess blood may be expelled from the cartridge.

The i-STAT PT/INR test can be performed using capillary or venous samples.

Skin Punctures

1. Remove cartridge from foil pouch and place the cartridge on a flat surface.

2. Prepare lancet device and set aside until needed.

3. Clean and prepare the finger to be sampled using a 70% aqueous solution of isopropanol (70% v/v).[5] Allow the finger to dry thoroughly before sampling. When disinfecting fingerstick skin puncture sites, swabs or solutions containing substances other than isopropanol (e.g., chlorhexidine gluconate) are not recommended. Refer to the "Limitations of the i-STAT PT/INR Test" section above for more information.

4. Prick the bottom side of the fingertip with the lancet device.

5. Gently squeeze the finger, developing a hanging drop of blood and perform the test with the first sample of blood. *Avoid strong repetitive pressure ("milking") as it may cause hemolysis or tissue fluid contamination of the specimen.*

6. Touch the drop of blood against the bottom of the sample well. Once in contact with the sample well, the blood will be drawn into the cartridge.

7. Apply sample until it reaches the fill mark indicated on the cartridge.

8. Fold the sample closure over the sample well.

9. Press the rounded end of the closure until it snaps into place.

Note: To further simplify the sample application into the test cartridge, it is possible to bring the cartridge to the finger for easier application. Do ensure that the instrument remains on a flat, vibration-free surface for testing.
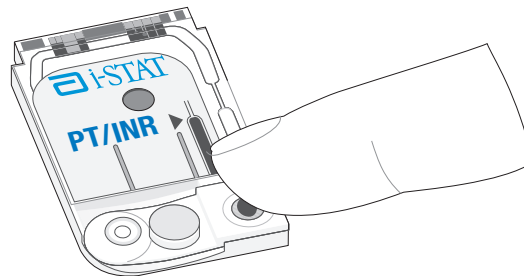
Venipunctures

- Collection technique resulting in good blood flow must be used.

- The sample for testing should be drawn into a **plastic collection device** (either a plastic syringe or plastic evacuated tube).

- The collection device **cannot contain anticoagulants** such as heparin, EDTA, oxalate, or citrate.

- The collection device **cannot contain clot activators or serum separators.**

- The sample should be immediately dispensed into the sample well of a cartridge. A drop of blood should be touched against the bottom of the sample well. Once in contact with the sample well, the blood will be drawn into the cartridge.

- If a second measurement is required, a fresh sample should be obtained.

Note: Some experts recommend drawing and discarding a (venous) sample of at least 1.0 mL prior to drawing sample for coagulation testing.[6]

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Abbott Point of Care Inc.
Abbott Park, IL 60064 • USA

EC | REP

EMERGO EUROPE
Molenstraat 15
2513 BH The Hague
The Netherlands
Tel: (31)70 345 8570
Fax: (31)70 346 7299

CE   IVD

CARDIAC TROPONIN I/ (cTnI)

Intended Use

The i-STAT® cardiac troponin I (cTnI) test is an *in vitro* diagnostic test for the quantitative measurement of cardiac troponin I (cTnI) in whole blood or plasma. Measurements of cardiac troponin I are used in the diagnosis and treatment of myocardial infarction and as an aid in the risk stratification of patients with acute coronary syndromes with respect to their relative risk of mortality.

Method Explanation

The i-STAT cTnI test cartridge uses a two-site enzyme-linked immunosorbant assay (ELISA) method. Antibodies specific for human cardiac troponin I (cTnI) are located on an electrochemical sensor fabricated on a silicon chip. Also deposited in another location on the sensor silicon chip is an antibody/alkaline phosphatase enzyme conjugate specific to a separate portion of the cTnI molecule. The whole blood or plasma sample is brought into contact with the sensors allowing the enzyme conjugate to dissolve into the sample. The cTnI within the sample becomes labeled with alkaline phosphatase and is captured onto the surface of the electrochemical sensor during an incubation period of approximately seven minutes. The sample, as well as excess enzyme conjugate, is washed off the sensors. Within the wash fluid is a substrate for the alkaline phosphatase enzyme. The enzyme bound to the antibody/antigen/antibody sandwich cleaves the substrate releasing an electrochemically detectable product. The electrochemical (amperometric) sensor measures this enzyme product which is proportional to the concentration of cTnI within the sample.

Contents

Each i-STAT cTnI cartridge provides a sample inlet, sensors to detect the cTnI as described above, and all the necessary reagents needed to perform the test. The cartridge contains a buffer and preservatives. A list of reactive ingredients is indicated below:

Reactive Ingredient	Biological Source	Minimum Quantity
Antibody/Alkaline Phosphatase Conjugate	Caprine IgG : Bovine Intestine	0.003 µg
IgG	Caprine IgG : Murine IgG	8 µg : 8 µg
Sodium Aminophenyl Phosphate	N/A	0.9 mg
Heparin	Porcine Intestine	0.45 IU
IgM	Murine IgM	0.3 µg

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Point of Care

Metrological Traceability

The i-STAT System test for cardiac troponin-I (cTnI) measures cardiac troponin-I amount-of-substance concentration in plasma or the plasma fraction of whole blood (dimension ng mL^{-1}) for *in vitro* diagnostic use. Cardiac troponin-I values assigned to i-STAT's controls and calibration verification materials are traceable to i-STAT's working calibrator prepared from human cardiac troponin-ITC complex (Hy-Test Ltd., Turku, Finland, catalogue #8T62). i-STAT System controls and calibration verification materials are validated for use only with the i-STAT System and assigned values may not be commutable with other methods. Further information regarding metrological traceability is available from Abbott Point of Care Inc.

Reportable Range

The i-STAT cTnI test will report 0.00 to 50.00 ng/mL (μg/L). Samples above the reportable range will yield ">50.00 ng/mL" on the analyzer display screen. However, the performance characteristics of the i-STAT cTnI measurement have not been established for cTnI values above 35.00 ng/mL (μg/L).

Reference Range

Whole blood and plasma samples from 162 apparently healthy donors were assayed in duplicate using three different lots of i-STAT cTnI cartridges. The 0 to 97.5% range of results spanned 0.00 ng/mL (μg/L) to 0.03 ng/mL (μg/L). The 0 to 99% range of results spanned 0.00 ng/mL (μg/L) to 0.08 ng/mL (μg/L).

Note: Each facility should establish its own reference range using the i-STAT cTnI assay.

Clinical Significance

Biochemical cardiac markers, including cTnI, are useful for both the diagnosis of myocardial infarction and the risk stratification that can help guide the choice of therapeutic options.

For optimal diagnostic usefulness, a cardiac marker should be specific for cardiac tissue, should be rapidly released into the bloodstream with a direct proportional relationship between the extent of myocardial injury and the measured level of the marker, and should persist in blood for a sufficient length of time to provide a convenient diagnostic time window.[1] The cardiac-specific troponins, troponin I (cTnI) and troponin T (cTnT) are considered the biochemical markers of choice in the evaluation of acute coronary syndromes (ACS) including ST-elevation myocardial infarction, non-ST-elevation myocardial infarction, and unstable angina.[2,3] Elevated levels of cardiac-specific troponins convey prognostic information beyond that supplied by the patients clinical signs and symptoms, the ECG at presentation, and the pre-discharge exercise test.[1] Antman et al. reported that patients with elevated levels of cTnI had a statistically significant increase in mortality (p< 0.001).[4] Other studies have shown increases in other non-fatal cardiac events such as non-fatal MI, congestive heart failure, and urgent revascularization with increasing levels of cTnI.[5,6,7]

The ability for cTnI to be measured at low concentrations allows therapeutic intervention to be considered at any elevation above the normal range. Patients that present with no ST-elevation on their ECG but who have even slight elevation in cTnI or cTnT may receive a greater treatment benefit from certain drugs such as GP IIb/IIIa inhibitors or low molecular weight heparin.[8,9,10]

A Global Task Force with joint leadership from the European Society of Cardiology (ESC), the American College of Cardiology Foundation (ACCF), the American Heart Association (AHA) and the World Heart Federation (WHF) refined past criteria of myocardial infarction with a universal definition of myocardial infarction that supports the use of cTnI as a preferred biomarker for myocardial injury. The universal definition of MI according to this task force is defined as a typical rise and gradual fall of cardiac biomarkers (preferably troponin) with at least one value above the 99th percentile of the upper reference limit (URL) together with evidence of myocardial ischemia with at least one of the following: ischemic symptoms, pathological Q waves on electrocardiogram (ECG), ischemic ECG changes, or imaging evidence of new loss of viable myocardium or new regional wall motion abnormality.[2] An elevated troponin value alone is not sufficient to diagnose a myocardial infarction. Rather, the patient's clinical presentation (history, physical

exam) and ECG should be used in conjunction with troponin in the diagnostic evaluation of suspected myocardial infarction.[3] A serial sampling protocol is recommended to facilitate the identification of temporal changes in troponin levels characteristic of MI.[2,3,11]

Since cTnI is not unequivocally detectable by commercial assays in samples from healthy persons, measurements beyond the upper limit of the reference range have a significant probability of being associated with ischemia or necrosis;[12] this probability increases with the measured troponin concentration. Nonetheless, by definition, results beyond the reference range will occur in a normal population in healthy individuals in the absence of myocardial necrosis, i.e., a result beyond the 99th percentile does not confirm the presence of troponin with absolute certainty. Each institution should determine the reference range and decision levels appropriate to its specific patient population and clinical practice.

Acute myocardial injury is evidenced by temporal changes in troponin levels while consistent elevations of troponin may be suggestive of other chronic cardiac or non-cardiac conditions. There are many clinical conditions that can lead to an elevated troponin level without ischemic coronary artery disease. Such conditions include blunt trauma, myocarditis, congestive heart failure, left ventricular hypertrophy etc.[13,14] These clinical conditions should be considered when interpreting results. The use of serial sampling with a consistent troponin methodology can identify temporal troponin changes, as well as provide additional information that can assist in the clinical diagnosis for those patients with low-level results. Where there are inconsistencies in the clinical information or where diagnostic criteria are not fully satisfied, the possibility of biased results should be recognized – see Test Limitations.

Performance Characteristics
Precision data were collected in multiple sites as follows: Duplicates of each control were tested daily for a period of 20 days, resulting in a total of 40 replicates. The average statistics are presented below.

Method comparison data were collected using CLSI guideline EP9-A2.[15] Venous blood samples were collected in heparinized evacuated tubes and analyzed in duplicate on the i-STAT System. A portion of the specimen was centrifuged and the separated plasma was analyzed in duplicate on the comparative method within 1 hour of collection.

Deming regression analysis[16] was performed on the first replicate of each sample. In the method comparison table, n is the number of specimens in the first data set, Sxx and Syy refer to estimates of imprecision based on the duplicates of the comparative and the i-STAT methods respectively. Sy.x is the standard error of the estimate, and r is the correlation coefficient.*

Method comparisons will vary from site to site due to differences in sample handling, comparative method calibration and other site specific variables.

Interference studies were based on CLSI guideline EP7.[17]

*The usual warning relating to the use of regression analysis is summarized here as a reminder. For any analyte, "if the data is a narrow range, the estimate of the regression parameters are relatively imprecise and may be biased. Therefore, predictions made from estimates may be invalid".[13] The correlation coefficient, r, can be used as a guide to assess the adequacy of the comparative method range in overcoming the problem. As a guide, the range of data can be considered adequate if r>0.975.

Precision Data (ng/mL)

Control	Mean	SD	%CV
Level 1	0.53	0.04	7.8
Level 2	2.17	0.18	8.5
Level 3	31.82	2.42	7.6

Method Comparison (ng/mL)

	Dade Behring Stratus® CS
n	189
Sxx	0.28
Syy	0.31
Slope	0.883
Int't	0.029
Sy.x	1.40
Xmin	0.00
Xmax	46.27
r	0.975

Analytical and Functional Sensitivities

The analytical sensitivity of the cTnI method is 0.02 ng/mL, which is the lowest cTnI level that can be distinguished from zero. The analytical sensitivity is defined as the concentration at two standard deviations from a sample at 0.00 ng/mL.

Another characteristic of an analytical measurement is the functional sensitivity, which is defined as the cTnI level at which the test method displays a particular percent coefficient of variation (%CV). Estimates of the 20% and 10% functional sensitivity for the cTnI method were determined from whole blood measurements. The 20% and 10% functional sensitivities for the cTnI method are 0.07 ng/mL and 0.10 ng/mL, respectively (see graph below).

i-STAT Method Imprecision vs cTnI Level
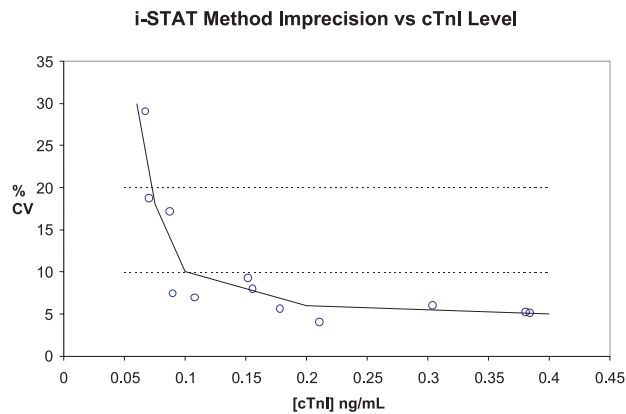
Analytical Specificity

The cTnI method is specific for cardiac troponin I. The following muscle proteins were tested and found to have an insignificant effect on the measured cTnI.

Crossreactant	Concentration	Percent Crossreactivity
Troponin C (cardiac)	1000 ng/mL	<0.002%
Troponin T (cardiac)	1000 ng/mL	0.65%
Troponin I (skeletal)	1000 ng/mL	<0.002%
Troponin T (skeletal)	1000 ng/mL	<0.002%

Recovery

The dilution linearity of the i-STAT cTnI test was investigated using heparinized whole blood and plasma samples derived from 3 separate donors. For each donor, the original cTnI negative sample and a cTnI spiked sample were prepared. This process yielded three cTnI positive whole blood samples that were then assayed in duplicate for each of three separate i-STAT cTnI cartridge lots. These whole blood samples were then diluted using an equal mass of the original unspiked whole blood and assayed in duplicate. From this whole blood data, the cTnI recovery was calculated.

The plasma derived from these three donors was combined in equal masses and all pairwise combinations. These combinations were then assayed in duplicate for each of three separate i-STAT cTnI cartridge lots. The cTnI recovery for each pair was calculated using the average of the 6 results. The % recoveries are listed in the Tables below.

Whole blood

Sample	Concentration	Diluted Concentration	% Recovery
A	2.05	1.04	101%
B	6.31	3.14	100%
C	27.04	14.05	104%

Plasma

Sample	Concentration	Diluted Concentration	% Recovery
A	2.41	-----	-----
B	7.50	-----	-----
C	29.35	-----	-----
A+B	-----	4.69	95%
B+C	-----	18.90	103%
A+C	-----	16.89	106%

Test Limitations

The frequency of suppressed results is affected by atmospheric pressure.   Suppressed result rates may increase with higher elevations (decreased barometric pressure) and may become persistent if testing is performed at more than 7500 feet above sea level. Where unavailability of results is unacceptable, i-STAT recommends having an alternate test method available.

Samples from patients who have been exposed to animals or who have received therapeutic or diagnostic procedures employing immunoglobulins or reagents derived from immunoglobulins may contain antibodies, e.g., HAMA or other heterophile antibodies, which may interfere with immunoassays and produce erroneous results.[18-24] The generation of potentially interfering antibodies in response to bacterial infections has been reported.[16] While this product contains reagents that minimize the effect of these interferents and QC algorithms designed to detect their effects, the possibility of interference causing erroneous results should be evaluated carefully in cases where there are inconsistencies in the clinical information. Results from the i-STAT cTnI assay should be considered in the context of the entirety of the available clinical information. Medical decisions should not be based on a single i-STAT measurement.[14]

Cardiac troponin may not appear in circulation for 4-6 hours following the onset of symptoms of MI. Consequently, a single negative result is insufficient to rule out MI. The use of a serial sampling protocol is recommended practice.[11]

The results of different troponin assays are not generally comparable: cTnI and cTnT are distinct molecules and results are not interchangeable, nor comparable. In addition, significant variation in absolute troponin values may be observed for a given patient specimen with different analytic methods.[13]

Partially clotted samples can result in elevated cTnI results above the reference range, as well as quality check code errors. To prevent this from occurring, upon drawing the whole blood sample into a heparinized collection tube, the sample should be inverted gently at least 10 times to ensure even dissolution of the heparin anticoagulant.

Grossly hemolyzed samples can cause a decreased alkaline phosphatase activity, resulting in decreased detection of cTnI, increased assay backgrounds, and/or quality check codes.

Hematocrits in the range of 0-65% PCV have been demonstrated not to affect results. Samples with hematocrit levels above this range have demonstrated increases in the test imprecision and quality check codes.

The analyzer must remain on a level surface with the display facing up during testing. Motion of the analyzer during testing can increase the frequency of suppressed results or quality check codes. A level surface includes running the handheld in the downloader/recharger.

Interference Testing

The following substances were found to have no significant effect (less than 10%) on the cTnI method, when added to a plasma pool containing approximately 2 ng/mL of cardiac troponin I, at the concentrations indicated:

Compound	Test Level (µmol/L unless otherwise indicated)
Acetaminophen	1660
Allopurinol	294
Ascorbic Acid	227
Acetyl Salicylic Acid	3330
Atenolol	37.6
Caffeine	308
Captopril	23
Chloramphenicol	155
Diclofenac	169
Digoxin	6.15
Dopamine	5.87
Enalaprilat	0.86
Erythromycin	81.6
Furosemide	181
Sodium Heparin*	36 U/mL
Ibuprofen	2425
Isosorbide dinitrate	636
Methyldopa	71
Nicotine	6.2
Nifedipine	1.156
Phenytoin	198
Propranolol	7.71
Salicylic Acid	4340
Theophylline	222
Verapamil	4.4
Warfarin	64.9

*Heparin at 90 U/mL was found to decrease the cTnI level by approximately 20%.

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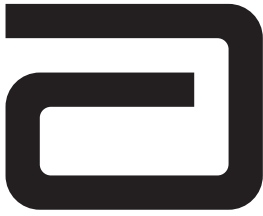
Abbott Point of Care Inc.
Abbott Park, IL 60064 • USA

EC REP

Emergo Europe
Molenstraat 15
2513 BH, The Hague
The Netherlands
Tel: (31)70 345 8570
Fax: (31)70 346 7299

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CREATINE KINASE MB/ (CK-MB)

Intended Use

The i-STAT® CK-MB test is an *in vitro* diagnostic test for the quantitative measurement of creatine kinase MB mass in whole blood or plasma samples. CK-MB measurements can be used as an aid in the diagnosis and treatment of myocardial infarction (MI).

Method Explanation

The i-STAT CK-MB test cartridge uses a two-site enzyme-linked immunosorbant assay (ELISA) method. Antibodies specific for an epitope unique to the CK-MB subunit, that therefore do not bind CK-MM or CK-BB, are located on an electrochemical sensor fabricated on a silicon chip. Also deposited in another location on the sensor silicon chip is an antibody/alkaline phosphatase enzyme conjugate specific to an epitope on the B subunit of creatine kinase. The specificity of the conjugate antibody to the B subunit allows this conjugate to recognize CK-MB and CK-BB, but not CK-MM. The whole blood or plasma sample is brought into contact with the sensors allowing the enzyme conjugate to dissolve into the sample. The CK-MB within the sample becomes labeled with alkaline phosphatase and is captured onto the surface of the electrochemical sensor during an incubation period of approximately three minutes. The sample is washed off the sensors, as well as excess enzyme conjugate. Within the wash fluid is a substrate for the alkaline phosphatase enzyme. The enzyme bound to the antibody/antigen/antibody sandwich cleaves the substrate releasing an electrochemically detectable product. The electrochemical (amperometric) sensor measures this enzyme product which is proportional to the concentration of CK-MB within the sample.

Contents

Each i-STAT CK-MB cartridge provides a sample inlet, sensors to detect the CK-MB as described above, and all the necessary reagents needed to perform the test. The cartridge contains a buffer and preservatives. A list of reactive ingredients is indicated below:

Reactive Ingredient	Biological Source	Minimum Quantity
Antibody/Alkaline Phosphatase Conjugate	Murine IgG : Bovine Intestine	0.013 µg
IgG	Caprine IgG : Murine IgG	4 µg
Sodium Aminophenyl Phosphate	N/A	0.9 mg
Heparin	Porcine Intestine	0.45 IU

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Metrological Traceability

The i-STAT System test for creatine kinase-MB (CK-MB) measures creatine kinase-MB amount-of-substance concentration mass in plasma or the plasma fraction of venous whole blood (dimension ng/mL) for *in vitro* diagnostic use. Creatine kinase-MB values assigned to i-STAT System controls are traceable to the American Association of Clinical Chemists (AACC recombinant human CK-MB from Seradyn Inc.) calibrator for the standardization of creatine kinase mass assays. i-STAT System controls and calibration verification materials are validated for use only with the i-STAT System and assigned values may not be commutable with other methods. Further information regarding metrological traceability is available from Abbott Point of Care Inc.

Reportable Range

The i-STAT CK-MB test will report 0.0 to 150.0 ng/mL (µg/L). Samples above the reportable range will yield ">150.0 ng/mL" on the analyzer display screen.

Reference Range

Whole blood and plasma samples from 161 apparently healthy donors were assayed in duplicate using three different lots of i-STAT CK-MB cartridges. The 0 to 95% range of results spanned 0.0 ng/mL (µg/L) to 3.5 ng/mL (µg/L).

Note: Each facility should establish its own reference range using the i-STAT CK-MB assay.

Clinical Significance

CK-MB mass has been reported to be useful for the diagnosis of myocardial infarction, re-infarction, and the sizing of infarction.

For optimal diagnostic usefulness, a cardiac marker should be specific for cardiac tissue, should be rapidly released into the bloodstream with a direct proportional relationship between the extent of myocardial injury and the measured level of the marker, and should persist in blood for a sufficient length of time to provide a convenient diagnostic time window.[1]

Creatine kinase (CK) is a dimeric enzyme found primarily in brain and muscle tissue. There are three isoforms of creatine kinase: BB, MM, and MB. BB is found primarily in the brain. Skeletal muscles primarily contain the MM isoform, with traces of MB (estimates of 1-4% of CK activity). Cardiac muscles also contain primarily the MM isoform, but higher amounts of MB, typically around 20% of CK activity.[2] Serum from healthy individuals typically contains the MM isoform and a small amount of the MB isoform. CK-MB can be released into the bloodstream by a number of actions, including skeletal muscle injury and myocardial damage.

The rise in CK-MB in the bloodstream occurs between 4-6 hours following a myocardial infarction (MI). The concentration peaks after approximately 24-hours and returns to baseline after 36-72 hours. As the level of CK-MB is not cardiac specific, the results of a single test are not indicative of a myocardial infarction (MI). Typically an MI is diagnosed based on the pattern of CK-MB analyses taken at 3-hour intervals for a 6- to-9 hour period or at 6- to-8 hour intervals for a 24-hour period.

Although the cardiac-specific troponins, troponin I (cTnI) and troponin T (cTnT) are now considered the biochemical markers of choice in the evaluation of acute coronary syndromes (ACS) including ST-elevation myocardial infarction, non-ST-elevation myocardial infarction, and unstable angina, CK-MB can also be used as a secondary marker to aid in the diagnosis of myocardial infarction and measuring the degree of myocardial necrosis. Since low levels of CK-MB can be detected in the blood of healthy persons, any CK-MB value above the 95th percentile may be indicative of some degree of myocardial necrosis.[1] Each institution should establish its own reference range for its patient population, and this range should be used to determine an appropriate limit indicative of acute myocardial infarction (AMI).

The European Society of Cardiology / American College of Cardiology consensus document notes that in the clinical setting of a reinfarction, CK-MB may be more useful for monitoring for MI than cardiac troponin I (cTnI) or cardiac troponin T (cTnT) because CK-MB remains increased for only 2-4 days following an MI,

in contrast to up to 5 days for cTnI or 10 days for cTnT.[3,4,5,6,7] Clinical studies have also demonstrated a close relationship between the extent of injury to the myocardium (infarct size) following MI and increased serum CK-MB mass concentrations.[8] Similarly, significant correlations have been observed between CK-MB estimated infarct sizing and left ventricular echocardiography.[8]

Other conditions involving skeletal muscle damage like accidents, blunt trauma, severe burns, and extreme exercise or myopathic disorders such as myocarditis that are not secondary to ischemic coronary artery disease can also lead to skeletal muscle or myocardial injury and have the potential to cause elevations in the blood concentrations of CK-MB. These conditions should be considered when interpreting results, and the CK-MB level should be used in conjunction with clinical symptoms, signs, patient history, and ECG changes.[1,9]

Performance Characteristics

Precision data were collected in multiple sites as follows: Duplicates of each control were tested daily for a period of 20 days for each of three lots of cartridges, resulting in a total of 120 replicates. The average statistics are presented below.

Method comparison data were collected using CLSI guideline EP9-A2.[10] Venous blood samples were collected in heparinized evacuated tubes and analyzed in duplicate on the i-STAT System. A portion of the specimen was centrifuged and the separated plasma was analyzed in duplicate on the i-STAT System and on the comparative method within 1 hour of collection.

Deming regression analysis[11] was performed on the first replicate of each sample. In the method comparison table, n is the number of specimens in the first data set, Sxx and Syy refer to estimates of imprecision based on the duplicates of the comparative and the i-STAT methods, respectively. Sy.x is the standard error of the estimate, and r is the correlation coefficient.*

Method comparisons may vary from site to site due to differences in sample handling, comparative method calibration and other site specific variables.

Interference studies were based on CLSI guideline EP7-A.[12]

*The usual warning relating to the use of regression analysis is summarized here as a reminder. For any analyte, "if the data is a narrow range, the estimate of the regression parameters are relatively imprecise and may be biased. Therefore, predictions made from estimates may be invalid",[10] The correlation coefficient, r, can be used as a guide to assess the adequacy of the comparative method range in overcoming the problem. As a guide, the range of data can be considered adequate if r>0.975.

Precision Data (ng/mL)

Plasma Control	Mean	SD	%CV
Level 1	5.9	0.7	11.9
Level 2	25.8	2.7	10.4
Level 3	90.1	9.0	10.0

Method Comparison (ng/mL)

	Abbott AxSYM
n	263
Sxx	1.84
Syy	2.66
Slope	1.01
Int't	-0.19
Sy.x	3.98
Xmin	0.04
Xmax	224
r	0.994

Analytical Sensitivities

The sensitivity of the CK-MB method is 0.6 ng/mL, which is the lowest CK-MB level that can be distinguished from zero. The analytical sensitivity is defined as two standard deviations associated with a zero calibrator. The analytical sensitivity was estimated using a control material with <1 ng/mL CK-MB during a 20-day precision study in which three separate lots of CK-MB test cartridges were tested in duplicate using a pool of six i-STAT 1 analyzers for a total of 120 test results.

Analytical Specificity

The CK-MB method is specific for the creatine kinase MB isoenzyme. The following muscle proteins were tested and found to have an insignificant effect on the measured CK-MB.

Crossreactant	Concentration	Percent Crossreactivity
CK-MM (skeletal)	10000 ng/mL	Not Detectable
CK-BB (brain)	100 ng/mL	Not Detectable

Recovery

The dilution linearity of the i-STAT CK-MB test was investigated using heparinized whole blood and plasma samples derived from three separate donors. For each donor, the original CK-MB negative sample and a CK-MB spiked sample were prepared. This process yielded three CK-MB positive whole blood samples that were then assayed in duplicate for each of three separate i-STAT CK-MB cartridge lots. These whole blood samples were then diluted using an equal mass of the original unspiked whole blood and assayed in duplicate. From this whole blood data, the CK-MB recovery was calculated.

The plasma derived from these three donors was combined in equal masses and all pairwise combinations. These combinations were then assayed in duplicate for each of three separate i-STAT CK-MB cartridge lots. The CK-MB recovery for each pair was calculated using the average of the six results. The % recoveries are listed in the Tables below.

Whole Blood

Sample	Concentration (ng/mL)	Diluted Concentration (ng/mL)	% Recovery
A	73.24	40.73	108.7%
B	8.90	6.07	101.5%
C	47.74	26.91	109.3%

Plasma

Sample	Concentration (ng/mL)	Diluted Concentration (ng/mL)	% Recovery
A	73.24	—	—
B	8.90	—	—
C	47.74	—	—
A+B	—	42.17	102.7%
B+C	—	30.85	108.9%
A+C	—	63.95	105.7%

Test Limitations

The frequency of suppressed results is affected by atmospheric pressure. Suppressed result rates may increase with higher elevations (decreased barometric pressure) and may become persistent if testing is performed at more than 7500 feet above sea level. Where unavailability of results is unacceptable, i-STAT recommends having an alternate test method available.

Samples from patients who have been exposed to animals or who have received therapeutic or diagnostic procedures employing immunoglobulins or reagents derived from immunoglobulins may contain antibodies, e.g., HAMA or other heterophile antibodies, which may interfere with immunoassays and produce erroneous results.[13-19] The generation of potentially interfering antibodies in response to bacterial infections has been reported.[13] While this product contains reagents that minimize the effect of these interferents, and QC algorithms designed to detect their effects, the possibility of interference causing erroneous results should be evaluated carefully in cases where there are inconsistencies in the clinical information.

Partially clotted samples can result in elevated CK-MB readings above the reference range, as well as quality check code errors. To prevent this from occurring, upon drawing the whole blood sample into a heparinized collection tube, the sample should be inverted gently at least 10 times to ensure even dissolution of the heparin anticoagulant.

Grossly hemolyzed samples can cause a decreased alkaline phosphatase activity, resulting in decreased detection of CK-MB, increased assay backgrounds, and/or quality check codes.

Hematocrits in the range of 0-70% PCV have been demonstrated not to affect results. Samples with hematocrit levels above this range have demonstrated increases in the test imprecision and quality check codes.

The analyzer must remain on a flat surface with the display facing up during testing. Motion of the analyzer during testing can increase the frequency of suppressed results or quality check codes. A level surface includes running the handheld in the downloader/recharger.

Interference Testing

When added to a plasma pool containing approximately 20 ng/mL of creatine kinase MB isoenzyme, the following substances were found to have no significant effect (less than 10%) on the CK-MB method at the concentrations indicated.

Compound	Test Level (μmol/L unless otherwise indicated)
Acetaminophen	1660
Allopurinol	294
Ampicillin	152
Ascorbic Acid	227
Acetyl Salicylic Acid	3330
Atenolol	37.6
Caffeine	308
Captopril	23
Chloramphenicol	155
Diclofenac	169
Digoxin	6.15
Dopamine	5.87
Enalaprilat	0.86
Erythromycin	81.6
Furosemide	181
Sodium Heparin	90 U/mL
Ibuprofen	2425
Isosorbide dinitrate	636
Methyldopa	71
Nicotine	6.2
Nifedipine	1156
Phenytoin	198
Propranolol	7.71
Salicylic Acid	4340
Theophylline	222
Verapamil	4.4
Warfarin	64.9

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Abbott Point of Care Inc.
Abbott Park, IL 60064 • USA

EC REP

Emergo Europe
Molenstraat 15
2513 BH, The Hague
The Netherlands
Tel: (31)70 345 8570
Fax: (31)70 346 7299

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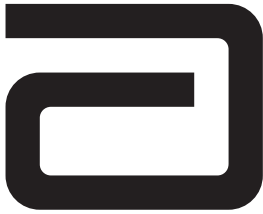
B-TYPE NATRIURETIC PEPTIDE/ (BNP)

Intended Use

The i-STAT® BNP test is an *in vitro* diagnostic test for the quantitative measurement of B-type natriuretic peptide (BNP) in whole blood or plasma samples using EDTA as the anticoagulant. BNP measurements can be used as an aid in the diagnosis and assessment of the severity of congestive heart failure.

Method Explanation

The i-STAT BNP test cartridge uses a two-site enzyme-linked immunosorbant assay (ELISA) method. Antibodies specific for BNP are located on an electrochemical sensor fabricated on a silicon chip. Also deposited in another location on the sensor silicon chip is an antibody/alkaline phosphatase enzyme conjugate specific to a separate portion of the BNP molecule. The whole blood or plasma sample is brought into contact with the sensors allowing the enzyme conjugate to dissolve into the sample. The BNP within the sample becomes labeled with alkaline phosphatase and is captured onto the surface of the electrochemical sensor during an incubation period of approximately seven minutes. The sample is washed off the sensors, as well as excess enzyme conjugate. Within the wash fluid is a substrate for the alkaline phosphatase enzyme. The enzyme bound to the antibody/antigen/antibody sandwich cleaves the substrate releasing an electrochemically detectable product. The electrochemical (amperometric) sensor measures this enzyme product which is proportional to the concentration of BNP within the sample.

Contents

Each i-STAT BNP cartridge provides a sample inlet, sensors to detect the BNP as described above, and all the necessary reagents needed to perform the test. The cartridge contains a buffer and preservatives. A list of reactive ingredients is indicated below:

Reactive Ingredient	Biological Source	Minimum Quantity
Antibody/Alkaline Phosphatase Conjugate	Murine IgG : Bovine Intestine	0.009 µg
IgG	Caprine IgG : Murine IgG	8.5 µg : 8 µg
Sodium Aminophenyl Phosphate	N/A	0.9 mg
Heparin	Porcine Intestine	0.45 IU
IgM	Murine IgM	0.3 µg

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Metrological Traceability

The i-STAT System test for B-type natriuretic peptide (BNP) measures BNP amount-of-substance concentration in plasma or the plasma fraction of EDTA anticoagulated whole blood (units of measure: pg/mL or ng/L) for *in vitro* diagnostic use. BNP values assigned to i-STAT's controls and calibration verification materials are traceable to i-STAT's working calibrator prepared from synthetic BNP (Peptide International, Louisville, KY, Cat# 4212v). i-STAT System controls and calibration verification materials are validated for use only with the i-STAT System and assigned values may not be commutable with other methods. Further information regarding metrological traceability is available from Abbott Point of Care Inc.

Reportable Range

The i-STAT BNP test will report 15 to 5000 pg/mL (ng/L). Samples below the reportable range will yield " <15 pg/mL" on the analyzer display screen. Samples above the reportable range will yield ">5000 pg/mL".

Reference Range

Whole blood and plasma samples from 165 apparently healthy donors were assayed. The upper 95% reference range was determined to be 50 pg/mL (ng/L).

Note: Each facility should establish its own reference range using the i-STAT BNP assay.

Clinical Significance

Congestive heart failure (CHF) is a complex clinical syndrome resulting in decreased cardiac output that is insufficient to meet the body's metabolic needs.[1] It may result from dysfunction of either ventricle in systole (contraction), diastole (relaxation) or both.[2] The most common underlying cause of CHF is coronary artery disease. Other causes include: hypertension, myocarditis, valvular heart disease and idiopathic (unknown).[3]

Common symptoms include: paroxysmal nocturnal dyspnea (PND), orthopnea, dyspnea on exertion (DOE), nocturnal cough and peripheral edema.[2] Clinical signs include elevated jugular venous pressure, rales on lung auscultation, the presence of a third heart sound and peripheral edema.[2] Unfortunately, these signs and symptoms are variable, and when present, non-specific as other clinical entities such as chronic obstructive pulmonary disease can produce a similar clinical picture.[4]

B-type natriuretic peptide (BNP) is one of a family of structurally similar peptide neurohormones that also includes atrial natriuretic peptide (ANP) and C-type natriuretic peptide (CNP) whose function is to regulate blood pressure, electrolyte balances, and fluid volume. ANP is stored in granules within the atria and released rapidly in response to atrial stretch. In contrast, BNP is synthesized, stored, and released primarily by the ventricular myocardium in response to volume expansion and pressure overload.[1] Pre-pro-BNP (134 amino acids) is synthesized in the cardiac myocytes and is processed to a pro-BNP (108 amino acids) precursor molecule. The pro-BNP is then subsequently cleaved into the physiologically active BNP (32 amino acids) and an N-terminal fragment referred to as N-Terminal pro-BNP (76 amino acids).[3]

Numerous clinical trials suggest the potential clinical usefulness of plasma BNP in:

1. the diagnosis of dyspnea and CHF[4,5]

2. the detection of left ventricular systolic and diastolic dysfunction[6,7]

3. the prognosis of patients with CHF and acute coronary syndromes[8,9] and

4. therapy monitoring for CHF patients[10,11]

Multiple studies establish the value of BNP for facilitating the diagnosis of CHF in patients presenting with dyspnea.[12] Davis et al. measured levels of ANP and BNP in 52 patients presenting with acute dyspnea.[12,13] They found that admission plasma BNP concentrations more accurately reflected the final diagnosis than did ejection fraction (EF) levels or ANP plasma concentrations. Morrison et al. also showed that rapid

testing of BNP could help differentiate pulmonary from cardiac etiologies of dyspnea.[4] Furthermore, the Task Force of the European Society of Cardiology for the Diagnosis and Treatment of Chronic HF has included the use of natriuretic peptide (e.g., BNP) testing along with electrocardiography and chest x-rays in their guidelines for the diagnosis or rule out of HF.[14]

The Breathing Not Properly study, a 1586 patient multinational prospective study, validated the clinical utility of rapid measurement of BNP, used in conjunction with other clinical information, for the diagnosis or exclusion of CHF in the emergency department.[15] BNP levels were much higher in patients with subsequent CHF than in those with non-cardiac dyspnea (675 pg/mL vs 110 pg/mL). A BNP cutoff value of 110 pg/mL had a sensitivity of 90% and a specificity of 76% for differentiating CHF from other causes of dyspnea, and a cutoff value of 50 pg/mL had a negative predicative value of 96%. There was a 43% indecision rate among physicians in the ED trying to make a diagnosis in patients with dyspnea. Had BNP levels been available to those physicians, the indecision rate would have been reduced to 11%. In multivariate analysis, BNP levels always contributed to the diagnosis, even after consideration of the history and physical exam.

BNP levels are also raised in patients with left ventricular dysfunction, and the values can be used to assess the severity of CHF, as they correlate with both New York Heart Association (NYHA) functional class and patient prognosis.[16]

Steg et al. indicated in 2005 that BNP measurement is consistently superior to a single echocardiographic determination of left ventricular EF in identifying patients with CHF, regardless of the threshold value.[16] Two-dimensional echocardiography was less sensitive than a single determination of BNP in diagnosing CHF. However, the two variables have marked additive diagnostic value and when combined have a much improved accuracy compared to either method alone. This strongly suggests that, where applicable, they should be used together.[16]

Studies also indicate that BNP also has a burgeoning role in the prognostic assessment of patients with heart failure.[17] BNP is a powerful prognostic indicator for patients with CHF at all stages of the disease and seems to be a better predictor of survival than many traditional prognostic indicators, such as New York Heart Association class, serum creatinine values, and possibly left ventricular ejection fraction.[18] The relative risk of death increases by about 35% for each 100 pg/mL increase in BNP in patients with CHF.[18] Raised BNP values also predict the survival in patients not known to have CHF, with the risk doubled in patients with a BNP value >20 pg/mL.[18]

BNP has also been shown to predict morbidity and mortality in other cardiovascular conditions, such as acute coronary syndromes and acute myocardial infarction.[19] ACS patients with increased BNP levels have a higher rate of cardiac complications and higher mortality post myocardial infarction.

When a panel of neurohormones (including BNP and catecholemines) was measured one to four days after acute infarction, BNP was the only independent predictor of late ejection fraction (EF <40%) and was the most powerful predictor of death within four months after infarction.[20] In 2,525 AMI patients, the magnitude of BNP elevation correlated with mortality, heart failure, and recurrent infarction at both 30 days and 10 months.[8] A strategy of combining EF and BNP improved risk stratification beyond using either alone.[21]

EXPECTED VALUES
Non-heart Failure Population

Plasma samples from 890 individuals (465 females, 425 males) who had not been diagnosed with heart failure were tested with the AxSYM® BNP assay. This population included non-hospitalized patients with renal disease (not on dialysis), diabetes, hypertension and chronic obstructive pulmonary disease. BNP levels for the patients with renal disease, diabetes, hypertension and chronic obstructive pulmonary disease were not statistically different from the population of apparently healthy individuals. The data from this study are summarized in the following table.*

Non-Heart Failure Population - All (Age Group)						
	All	<45 Years	45-54 Years	55-64 Years	65-74 Years	75+ Years
Sample Size (N=)	890	205	146	171	248	120
Median (pg/mL)	21	17	9	24	23	31
Mean (pg/mL)	39	28	21	37	47	63
SD (pg/mL)	66	36	30	48	80	109
95th Percentile	135	85	87	119	160	254
Percentage < 100 pg/mL	91.5%	96.6%	95.2%	94.2%	87.1%	83.3%
Minimum (pg/mL)	0	0	0	0	0	0
Maximum (pg/mL)	907	263	142	380	907	837

Non-Heart Failure Population - Males (Age Group)						
	All	<45 Years	45-54 Years	55-64 Years	65-74 Years	75+ Years
Sample Size (N=)	425	107	71	94	115	38
Median (pg/mL)	14	12	1	17	21	37
Mean (pg/mL)	30	23	9	26	47	49
SD (pg/mL)	61	34	14	45	96	51
95th Percentile	104	73	40	80	150	121
Percentage < 100 pg/mL	94.8%	97.2%	100.0%	97.9%	88.7%	89.5%
Minimum (pg/mL)	0	0	0	0	0	0
Maximum (pg/mL)	907	200	57	380	907	254

Non-Heart Failure Population - Females (Age Group)						
	All	<45 Years	45-54 Years	55-64 Years	65-74 Years	75+ Years
Sample Size (N=)	465	98	75	77	133	82
Median (pg/mL)	26	23	23	37	23	25
Mean (pg/mL)	46	34	34	51	46	69
SD (pg/mL)	70	37	36	48	63	126
95th Percentile	150	89	111	155	159	266
Percentage < 100 pg/mL	88.4%	95.9%	90.7%	89.6%	85.7%	80.5%
Minimum (pg/mL)	0	0	0	0	0	0
Maximum (pg/mL)	837	263	142	230	374	837

* Representative data, results in individual laboratories may vary from these data.

Due to demographic population differences, the reference range should be established at each laboratory.

Heart Failure Population

Plasma samples from 693 patients with diagnosed heart failure (231 females, 462 males) were tested with the AxSYM BNP assay. All patients in this population were categorized according to the functional classification system published by the New York Heart Association (NYHA).[22] This system divides heart failure patients into one of four categories of increasing disease progression (classes I to IV) based upon a subjective assessment of the patient's clinical signs and symptoms. The data from this study are summarized in the following table.*

Heart Failure Population - All					
		NYHA Functional Class			
	All	I	II	III	IV
Sample Size (N=)	693	124	319	190	60
Median (pg/mL)	298	133	266	335	1531
Mean (pg/mL)	578	320	432	656	1635
SD (pg/mL)	771	388	574	841	1097
5th Percentile	14	9	15	12	188
95th Percentile	2154	1257	1534	2516	>4000
Percentage ≥ 100 pg/mL	74.2%	58.1%	73.0%	79.0%	98.3%
Minimum (pg/mL)	0	3	0	0	14
Maximum (pg/mL)	>4000	1651	>4000	>4000	>4000

Heart Failure Population - Males

	NYHA Functional Class				
	All	**I**	**II**	**III**	**IV**
Sample Size (N=)	462	94	215	121	32
Median (pg/mL)	268	122	258	293	1645
Mean (pg/mL)	524	314	409	597	1646
SD (pg/mL)	719	390	539	821	1032
5th Percentile	12	9	14	22	265
95th Percentile	1976	1281	1356	2288	3654
Percentage ≥ 100 pg/mL	71.0%	56.4%	70.7%	76.0%	96.9%
Minimum (pg/mL)	0	3	0	0	14
Maximum (pg/mL)	>4000	1408	3782	>4000	>4000

Heart Failure Population - Females

	NYHA Functional Class				
	All	**I**	**II**	**III**	**IV**
Sample Size (N=)	231	30	104	69	28
Median (pg/mL)	385	174	298	466	1408
Mean (pg/mL)	685	341	481	760	1623
SD (pg/mL)	858	388	641	870	1186
5th Percentile	16	14	21	12	244
95th Percentile	2593	1022	2031	2718	>4000
Percentage ≥ 100 pg/mL	80.5%	63.3%	77.9%	84.1%	100.0%
Minimum (pg/mL)	0	10	0	0	173
Maximum (pg/mL)	>4000	1651	>4000	>4000	>4000

* Representative data, results in individual laboratories may vary from these data.

A box and whiskers plot of the clinical study population, broken down by NYHA classification, is presented in the following graph. The dashed line represents 100 pg/mL, the suggested decision threshold for the AxSYM BNP assay. In support of previous literature reports,[23] these data show a progressive increase in BNP concentrations with increases in NYHA classifications. This analysis indicates that BNP measurements provide objective information for use in the assessment of the severity of heart failure.
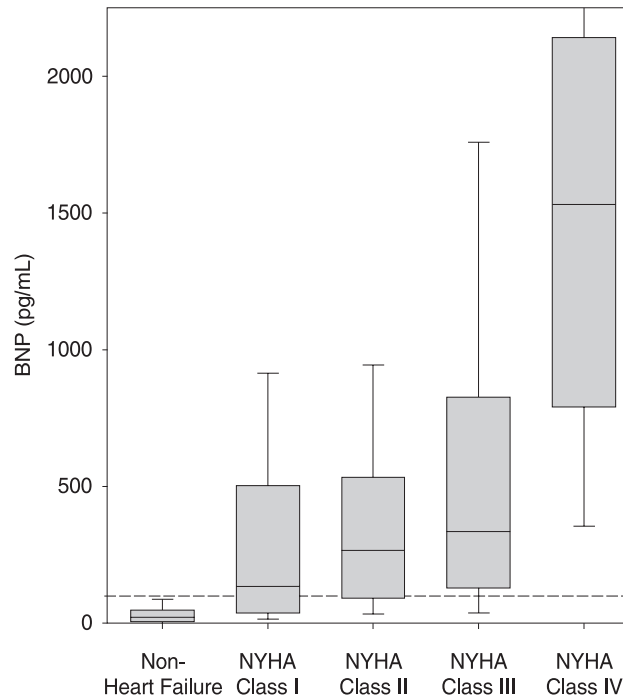
Data from the above clinical study were used to generate the Receiver Operating Characteristic (ROC) curve of BNP decision thresholds versus clinical sensitivity and clinical specificity as shown in the following graph. At a decision threshold of 100 pg/mL, the BNP assay demonstrated a clinical sensitivity and specificity of 74.2% and 91.5%, respectively, in this study. The area under the curve (AUC) is 0.90 (0.86 to 0.92, 95% CI).

BNP ROC Curve
Heart Failure Population (n=693) and
Non-Heart Failure Population (n=890)
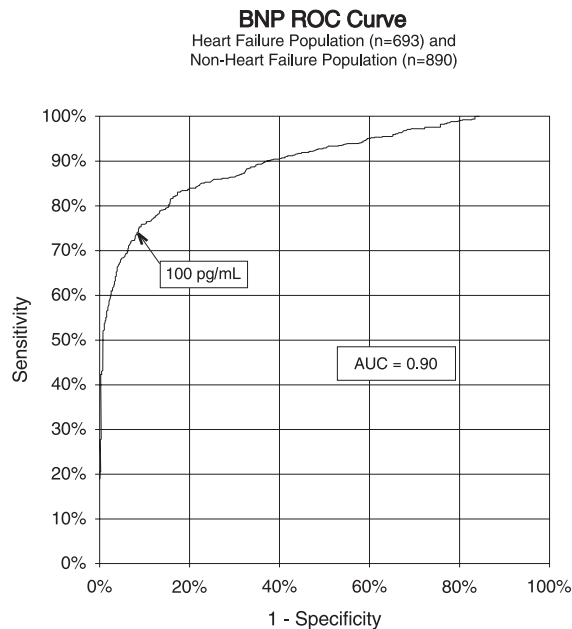
The i-STAT BNP Calibrators are traceable to an internal reference standard that has been prepared gravimetrically with synthetic BNP. The internal reference standard underwent a one-time value assignment to align with the ARCHITECT BNP assay with a decision threshold of 100 pg/mL.

An age-matched analysis of the heart failure and non-heart failure populations was performed based on the data published by the American Heart Association in the 2000 Heart and Stroke Statistical Update[24] and according to the age structure of the United States population.[25] The age distributions in the intended use population are approximately as follows: individuals less than 45 years old comprise 9%, individuals 45-54 years old comprise 11%, individuals 55-64 years old comprise 22%, individuals 65-74 years old comprise 26%, and individuals 75 years and older comprise 32%. The resulting combined AUC is 0.87 (0.85 to 0.90, 95% CI).

The clinical sensitivity and specificity using a decision threshold of 100 pg/mL is presented in the following table.*

Males (Age Group)						
	All	<45 Years	45-54 Years	55-64 Years	65-74 Years	75+ Years
Sensitivity	71.0% (328/462)	47.1% (8/17)	57.1% (24/42)	57.3% (51/89)	70.6% (115/163)	86.1% (130/151)
95% Confidence Interval	66.6 to 75.1%	23.0 to 72.2%	41.0 to 72.3%	46.4 to 67.7%	62.9 to 77.4%	79.5 to 91.2%
Specificity	94.8% (403/425)	97.2% (104/107)	100.0% (71/71)	97.9% (92/94)	88.7% (102/115)	89.5% (34/38)
95% Confidence Interval	92.3 to 96.7%	92.0 to 99.4%	94.9 to 100.0%	92.5 to 99.7%	81.5 to 93.8%	75.2 to 97.1%

Females (Age Group)						
	All	<45 Years	45-54 Years	55-64 Years	65-74 Years	75+ Years
Sensitivity	80.5% (186/231)	44.4% (4/9)	73.3% (11/15)	50.0% (13/26)	80.6% (58/72)	91.7% (100/109)
95% Confidence Interval	74.8 to 85.4%	13.7 to 78.8%	44.9 to 92.2%	29.9 to 70.1%	69.5 to 88.9%	84.9 to 96.2%
Specificity	88.4% (411/465)	95.9% (94/98)	90.7% (68/75)	89.6% (69.77)	85.7% (114/133)	80.5% (66/82)
95% Confidence Interval	85.1 to 91.2%	89.9 to 98.9%	81.7 to 96.2%	80.6 to 95.4%	78.6 to 91.2%	70.3 to 88.4%

* Representative data, results in individual laboratories may vary from these data.

Performance Characteristics

Precision data were collected as follows: Duplicates of each control were tested daily for a period of 20 days for each of 3 lots of cartridges, resulting in a total of 434 replicates. The average statistics are presented below.

Whole blood imprecision data were collected as follows: whole blood samples from 5 healthy donors were spiked to low, intermediate and high BNP concentrations affording 15 samples, each of which was measured in 10 i-STAT BNP cartridges from a single cartridge lot; three lots of cartridges were employed. The mean within-sample BNP concentration ranged from 84 – 3925 pg/mL and the within-sample imprecision (%CV) ranged from 3.4 to 9.4%; the average BNP concentration and imprecision were 1464 pg/mL and 6.5% respectively.

Method comparison data were collected using CLSI guideline EP9-A2.[26] Venous blood samples were collected in EDTA evacuated tubes and analyzed in duplicate on the i-STAT System. A portion of the specimen was centrifuged and the separated plasma was analyzed in duplicate on the i-STAT System and on the comparative method within 1 hour of collection. Deming regression analysis[27] was performed on the first replicate of each sample. In the method comparison table, n is the number of specimens in the first data set, Sxx and Syy refer to estimates of imprecision based on the duplicates of the comparative and the i-STAT methods respectively. Sy.x is the standard error of the estimate, and r is the correlation coefficient.* Method comparisons may vary from site to site due to differences in sample handling, comparative method calibration and other site specific variables.

The i-STAT BNP assay is designed for quantitation of BNP in whole blood or plasma samples. A series of samples for comparison of whole blood and plasma results was prepared from blood drawn from 25 nominally healthy donors. For each donor, whole blood (unspiked) and plasma obtained via centrifugation were first run simultaneously in duplicate i-STAT BNP test cartridges. A whole blood sample was then spiked with BNP and, following a short equilibration period, a plasma sample was prepared by centrifugation and the whole blood and plasma samples were run simultaneously in duplicate. Three lots of i-STAT BNP test cartridges were employed with a single lot being used for each donor. The results of Deming regression of whole blood vs plasma (x-axis) correlation data are summarized below for all samples ([BNP] < 5000 pg/mL) and separately for samples with [BNP] < 1000 pg/mL.

*The usual warning relating to the use of regression analysis is summarized here as a reminder. For any analyte, "if the data is a narrow range, the estimate of the regression parameters are relatively imprecise and may be biased. Therefore, predictions made from estimates may be invalid".[26] The correlation coefficient, r, can be used as a guide to assess the adequacy of the comparative method range in overcoming the problem. As a guide, the range of data can be considered adequate if r>0.975.

Precision Data (pg/mL)

Aqueous Control	Mean	%CV (within-run)	%CV (total)
Level 1	126	9.0	11.1
Level 2	1551	6.6	8.1
Level 3	3337	8.0	9.8

Method Comparison

	Abbott ARCHITECT
N	433
Mean (pg/mL)	482.1
Sxx (pg/mL)	38.1
Syy (pg/mL)	97.6
Slope	0.971
Intercept	-14.4
Sy.x	198.0
Xmin	5
Xmax	4797.7
Correlation, r	0.972

Equivalence of Whole Blood and Plasma (x-axis)

	Plasma([BNP]<5000pg/mL)	Plasma([BNP]<1000pg/mL)
N	49	36
Mean (pg/mL)	776	146
Sxx (pg/mL)	122.0	18.5
Syy (pg/mL)	98.1	16.5
Slope	0.946	1.01
Intercept	50.2	-0.2
Sy.x	107.3	28.3
Xmin	0	0
Xmax	4173	922
Correlation,r	0.997	0.996

Analytical Sensitivity

The limit of blank (commonly termed analytical sensitivity) was estimated at 14 pg/mL by calculating two times the total imprecision determined using a BNP-depleted plasma material (measured to be <5 pg/mL BNP) over a 20-day imprecision study using three separate lots of BNP cartridges and six i-STAT 1 analyzers.

Analytical Specificity

The BNP method is specific for the B-type natriuretic peptide. The following muscle proteins were tested at both 1000 pg/mL and 20000 pg/mL concentrations and found to have no detectable crossreactivity for BNP: ANP, CNP, and N-terminal pro-BNP.

Recovery

The dilution linearity of the i-STAT BNP test was investigated using EDTA whole blood and plasma samples derived from three separate donors. For each donor, the original BNP negative sample and a BNP spiked sample were prepared. This process yielded three BNP positive whole blood samples that were then assayed in duplicate for each of three separate i-STAT BNP cartridge lots. These whole blood samples were then diluted using an equal mass of the original unspiked whole blood and assayed in duplicate. From this whole blood data, the BNP recovery was calculated.

Whole Blood Sample	Concentration (pg/mL)	Diluted Concentration (pg/mL)	% Recovery
A	590	312	106%
B	2765	1429	103%
C	5123	2803	109%

The plasma derived from these three donors was combined in all pairwise combinations in equal volumes. These combinations were then assayed in duplicate for each of three separate i-STAT BNP cartridge lots. The BNP recovery for each pair was calculated using the average of the six results.

Plasma Blood Sample	Concentration pg/mL)	Diluted Concentration (pg/mL)	% Recovery
A	590	—	—
B	2764	—	—
C	5123	—	—
A+B	—	1570	94%
B+C	—	3992	101%
A+C	—	2734	96%

A plasma sample was spiked with BNP to a value of approximately 5000 pg/mL and the concentration was determined by duplicate measurements with i-STAT BNP test cartridges; the result was found to be within 200 pg/mL of the intended target. This sample was subjected to a series of dilutions with fresh, unspiked plasma in order to prepare a range of concentrations. The concentration of each sample/dilution was calculated based on the measured concentration of the initial solution and the dilutions performed. The diluted samples were then measured in i-STAT BNP test cartridges (N = 6-10). The procedure was repeated with a whole blood sample. The results of these experiments are summarized in the following table.

Sample	Dilution	Calculated [BNP] (pg/mL)	Measured [BNP] (pg/mL)	%Recovery
Plasma	1	52	57	110%
Plasma	2	104	114	110%
Plasma	3	259	265	103%
Plasma	4	518	560	108%
Plasma	5	1036	1002	97%
Plasma	6	2072	2277	110%
Plasma	7	3107	3384	109%
Plasma	8	4143	4222	102%
Whole Blood	1	44	41	93%
Whole Blood	2	88	88	100%
Whole Blood	3	269	287	107%
Whole Blood	4	537	554	103%
Whole Blood	5	725	720	99%
Whole Blood	6	1450	1367	94%
Whole Blood	7	3042	2826	93%
Whole Blood	8	4056	3856	95%

Test Limitations

The frequency of suppressed results is affected by atmospheric pressure.   Suppressed result rates may increase with higher elevations (decreased barometric pressure) and may become persistent if testing is performed at more than 7500 feet above sea level. Where unavailability of results is unacceptable, i-STAT recommends having an alternate test method available.

Samples from patients who have been exposed to animals or who have received therapeutic or diagnostic procedures employing immunoglobulins or reagents derived from immunoglobulins may contain antibodies, e.g., HAMA or other heterophile antibodies, which may interfere with immunoassays and produce erroneous results.[28-34] The generation of potentially interfering antibodies in response to bacterial infections has been reported.[28] While this product contains reagents that minimize the effect of these interferents and QC algorithms designed to detect their effects, the possibility of interference causing erroneous results should be evaluated carefully in cases where there are inconsistencies in the clinical information.

Partially clotted samples can result in elevated BNP readings above the reference range, as well as quality check codes. To prevent this from occurring, upon drawing the whole blood sample into an EDTA collection tube, the sample should be inverted gently at least 10 times to ensure even dissolution of the anticoagulant.

Grossly hemolyzed samples can cause a decreased alkaline phosphatase activity, resulting in decreased detection of BNP, increased assay backgrounds, and/or quality check codes.

Hematocrits in the range of 0-60% PCV have been demonstrated not to affect results. Samples with hematocrit levels above this range have demonstrated increases in the test imprecision and quality check codes.

The analyzer must remain on a flat surface with the display facing up during testing. Motion of the analyzer during testing can increase the frequency of suppressed results or quality check codes. A level surface includes running the handheld in the downloader/recharger.

Measurements of BNP should occur prior to nesiritide (Natrecor) recombinant BNP treatment, or 2 hours post-treatment.[35]

Interference Testing

The following substances were found to have no significant effect (less than 10%) on the BNP method, when added to a plasma pool containing approximately 1000 pg/mL of B-type natriuretic peptide at the concentrations indicated:

Interference studies were based on CLSI guideline EP7-A.[36]

Compound	Test Level (µmol/L unless otherwise indicated)
Acetaminophen	1660
Allopurinol	294
Ampicillin	152
Ascorbic Acid	227
Acetyl Salicylic Acid	3330
Atenolol	37.6
Caffeine	308
Captopril	23
Chloramphenicol	155
Diclofenac	169
Digoxin	6.15
Dopamine	5.87
Enalaprilat	0.86
Erythromycin	81.6
Furosemide	181
Sodium Heparin	90 U/mL
Ibuprofen	2425
Isosorbide dinitrate	636
Methyldopa	71
Nicotine	6.2
Nifedipine	1156
Phenytoin	198
Propranolol	7.71
Salicylic Acid	4340
Theophylline	222
Verapamil	4.4
Warfarin	64.9

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Abbott Point of Care Inc.
Abbott Park, IL 60064 • USA

EC | REP

Emergo Europe
Molenstraat 15
2513 BH, The Hague
The Netherlands
Tel: (31)70 345 8570
Fax: (31)70 346 7299

CE

IVD
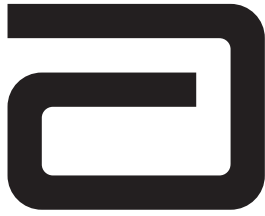
TOTAL BETA-HUMAN CHORIONIC GONADOTROPIN (β-hCG)

INTENDED USE

The i-STAT® Total Beta-Human Chorionic Gonadotropin (β-hCG) test is an *in vitro* diagnostic test for the quantitative and qualitative determination of β-hCG in venous whole blood or plasma samples using the i-STAT 1 Analyzer Systems. The test is intended to be used as an aid in the early detection of pregnancy and is for prescription use only.

SUMMARY AND EXPLANATION OF THE TEST

Human chorionic gonadotropin (hCG) is a glycoprotein hormone that is secreted by the syncytiotropho-blastic cells of the placenta. It is a complex molecule, consisting of two antigenically different glycoprotein subunits, alpha (α) and beta (β). The α subunit is found in other pituitary glycoprotein hormones (luteinizing hormone [LH], follicle stimulating hormone [FSH] and thyroid stimulating hormone [TSH]), as well as hCG. The β subunit is specific to hCG, yet exhibits considerable homology with LH. Both the intact hCG molecule and the free subunit are found in early pregnancy. Both β forms (intact and free) are detected by this test.

Physiologically, hCG appears to maintain the corpus luteum, thereby allowing synthesis of progesterone and estrogens that support the endometrium. Generally, as pregnancies progress, the placenta assumes the production of these hormones. hCG levels increase to a peak concentration, then decrease and plateau. Generally, hCG circulates as the intact molecule. The subunits are cleaved rapidly and cleared by the kidneys.[1]

BIOLOGICAL PRINCIPLES OF THE PROCEDURE

The i-STAT Total β-hCG test uses a two-site enzyme-linked immunosorbant assay (ELISA) method. Antibodies specific for β-hCG are located on an electrochemical sensor fabricated on a silicon chip. Also deposited in another location on the sensor silicon chip is an anti-βhCG antibody/alkaline phosphatase enzyme conjugate specific to a separate portion of the β subunit of the hCG molecule. The system is capable of detecting whole molecule (intact) hcg as well as the free β subunit, but not the β core fragment (β subunit missing the carboxyl terminal end). The whole blood or plasma sample is brought into contact with the sensors allowing the enzyme conjugate to dissolve into the sample. The hCG within the sample becomes labeled with alkaline phosphatase and is captured onto the surface of the electrochemical sensor during an incubation period of approximately seven minutes. The sample, as well as excess enzyme conjugate, is washed off the sensors. Within the wash fluid is a substrate for the alkaline phosphatase enzyme. The enzyme bound to the antibody/antigen/antibody sandwich cleaves the substrate, releasing an electrochemically detectable product. The electrochemical (amperometric) sensor measures this enzyme product, which is proportional to the concentration of β-hCG within the sample. Also positioned on the silicon chip is a (conductivity) sensor to assess the hematocrit value of the sample. This value is required in the calculation of the β-hCG concentration in whole blood samples.

For additional information on the system, refer to the i-STAT 1 System Manual.

Abbott
Point of Care

REAGENTS

Each i-STAT Total β-hCG cartridge contains all the necessary reagents for the test. A list of reactive ingredients is provided below:

Reactive Ingredient	Biological Source	Minimum Quantity
Antibody/Alkaline Phosphatase Conjugate	Murine IgG : Bovine Intestine	0.003 µg
IgG	Murine IgG	8 µg
IgM	Murine IgM	3 µg
Sodium Aminophenyl Phosphate	N/A	1.8 mg
Heparin	Porcine Intestine	0.45 IU

Warnings and Precautions

For *in vitro* diagnostic purposes.

Although the sample is contained within the cartridge, cartridges should be disposed of as biohazardous waste according to local, state, and national regulatory guidelines.

For additional warnings and precautions pertaining to the i-STAT System, refer to the i-STAT 1 System Manual.

Cartridge Storage Instructions

When refrigerated at 2-8 °C (35-46 °F), cartridges are stable until the expiration date. Cartridges may be stored at room temperature at 18-30 °C (64-86 °F) for the timeframe indicated on the cartridge box. Individual cartridges may be used after standing five minutes at room temperature. An entire box of cartridges should stand at room temperature for one hour prior to use. All cartridges should be used immediately after opening the portion pack (individual cartridge package). If the portion pack has been punctured, the cartridge should not be used.

INSTRUMENTS

For a detailed description of the instrument and system procedures, refer to the i-STAT 1 System Manual.

Customizing the Handheld to Display a Qualitative β-hCG Result

The default setting on the handheld displays a quantitative β-hCG value as well as a qualitative interpretation of the β-hCG test result. The handheld can be customized to disable or enable the qualitative β-hCG interpretation.

Quantitative β-hCG Result	Qualitative β-hCG Interpretation	Handheld Display
< 5.0 IU/L	Negative	hCG QUAL (-)
5.0 – 25.0 IU/L	Indeterminate	hCG QUAL ( )
>25.0 IU/L	Positive	hCG QUAL (+)

A. Customizing the Handheld to Disable or Enable the Qualitative β-hCG Result Using the Handheld Keypad:

1. Press ⏻ to turn on the handheld

2. Press (MENU) to change screen to Administration Menu

3. Press (4) (Customization)

4. Press (2) (Change)

5. Press (ENT) (no password is required)

6. Press (5) (Results)

7. Press (1) (Units and Ranges)

8. Press (➡) to scroll to the page that displays hCG Qual

9. Press (5) (hCG)

10. Press (1) (Disabled) OR (2) (Enabled)

11. Press ⏻ to turn handheld off and save the settings.

B. Customizing the Handheld to Disable or Enable the Qualitative β-hCG Result Using the Central Data Station (CDS Version 5)

1. Click on **Main - Open Administration Function - Customization.**
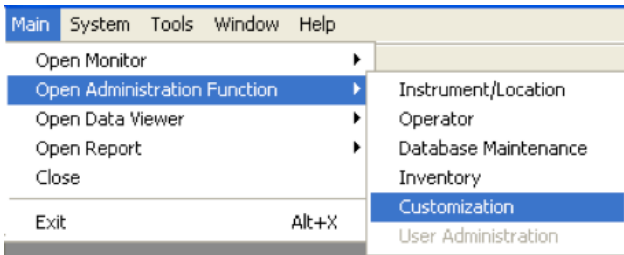
2. Type in your password and click **OK**. The default password is the word istat.
   Note: Abbott Point of Care recommends changing the default password.

3. Make sure the "**Enable Customization**" box has a check mark in it.
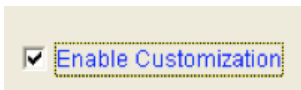
Also, make certain that the "**Enable Updates**" box is checked for the particular location to which this i-STAT 1 Analyzer is assigned.

Location-based customization profiles:

Location	Enable Updates	Use Default Profile	Update CLEW	i-STAT Analyzer CLEW	Philips BAM CLEW	Preferences	STATNotes
Site 001	✔	✔	✔	A22		11614WG2	CHART0
Site 002	✔	✔	✔	A22		11614WG2	CHART0

4. If the location where this handheld is assigned has a check mark under the **Use Default Profile** column, double click on the alphanumeric code under **Preferences** in the **Default Customization Profile** column. Otherwise, double click on the alphanumeric code under **Preferences** for the specific location to which this handheld is assigned.
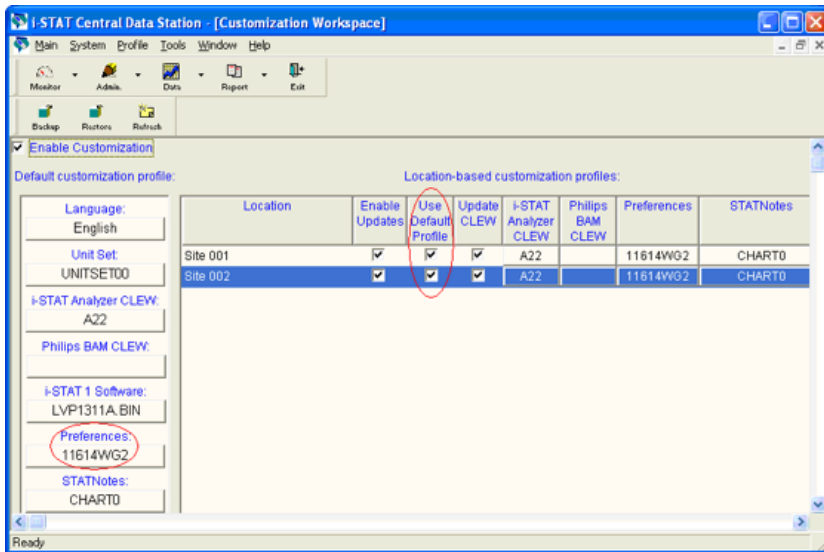
5. Once the **Preferences** screen opens, click on the "**Analyte Enable**" tab.

6. In the **Apply by Panel** section of the screen, select BhCG in the **Panel** column. The default setting has qualitative hCG enabled. To disable the qualitative hCG result, click the box beside the hCG analyte in the **Enable** column to clear the check mark. *OR* To enable the qualitative hCG result, check the box beside the hCG analyte in the **Enable** column.

7. Click **OK** and answer **YES** to the question about changing the preferences.

8. Download the handheld(s) to the CDS from a downloader in the location to which the handheld is assigned. This action will upload the chosen customization features into the handheld. Repeat step 8 for all handhelds from the same location to be customized. To customize handhelds from other locations for the same features, return to step 1 of this section.

C. Customizing the Analyzer to Disable or Enable the Qualitative β-hCG Result Using i-STAT/DE

1. Access the Customization Workspace
   - RALS-Plus Users:
     – Within the RALS-Plus application, pick **i-STAT** from the drop-down menu.
     – Click on **Device Customization**.
   - PrecisionWeb Users:
     – Enter the DE i-STAT Customization Workspace.

2. Make sure the "**Enable Customization**" box has a check mark in it.

   Also, make certain that the **Enabled** box is checked for the particular location to which the i-STAT 1 Analyzer is assigned.

3. If the location where this handheld is assigned has a check mark under **Uses Default**, under the **Default customization profile**: column, double click the alphanumeric code under **Preferences**. Otherwise, double click the alphanumeric code under the **Preferences** column for the specific location to which this handheld is assigned.

4. Once the **Preferences** window opens, click on the A**nalyte Enable** tab.

5. In the **Apply by Panel** section of the screen, select BhCG in the **Panel** column. The default setting has qualitative hCG enabled. To disable the qualitative hCG result, click the box beside the hCG analyte in the **Enable** column to clear the check mark. *OR* To enable the qualitative hCG result, check the box beside the hCG analyte in the **Enabled** column.
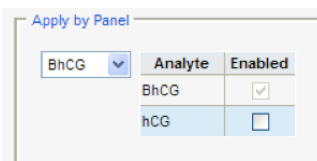
6. Click **OK** and answer **OK** to the question about changing the Preferences.
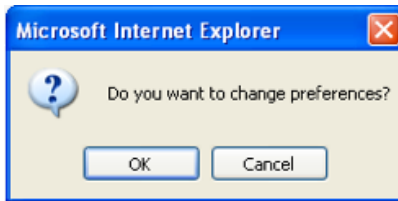
7. Download the handheld(s) to the Data Manager from a downloader in the location to which the hand-held is assigned. This action will upload the chosen customization features into the handheld. Repeat step 7 for all handhelds from the same location to be customized. To customize handhelds from other locations for the same features, return to step 1 of this section.

Performing Patient Analysis

1. Press ⏻ to turn on handheld.

2. Press ② for i-STAT cartridge.

3. Follow handheld prompts

4. Scan the lot number on the cartridge portion pack.

   • Position barcode 3 – 9 inches from scanner window on the handheld

   • Press and hold SCAN to activate the scanner

   • Align the red laser light so it covers the entire barcode

   • The handheld will beep when it reads the barcode successfully

5. Continue normal procedures for preparing the sample, filling, and sealing the cartridge

6. Push the sealed cartridge into the handheld port until it clicks into place. Wait for the test to complete.

SPECIMEN COLLECTION AND PREPARATION FOR ANALYSIS

Special Precautions

The i-STAT Total β-hCG cartridge requires a minimum sample volume of 17 µL to fill. Reported results will not be impaired by excess amounts beyond this requirement. However, excess blood or plasma will be present at the inlet of the cartridge and caution should be observed in handling the cartridge to minimize biohazard exposure.

Maintaining Sample Integrity

The i-STAT Total β-hCG test requires the use of heparinized whole blood or plasma samples collected in plastic syringes or evacuated tubes containing lithium or sodium heparin, filled to capacity.

Samples collected with the above mentioned anticoagulant are to be tested within 30 minutes after collection. Remix thoroughly before testing.

Known Interfering substances

The use of whole blood or plasma samples containing other anticoagulants such as EDTA, oxalate and citrate will cause deactivation of the alkaline phosphatase, resulting in decreased β-hCG readings.

PROCEDURE

For a detailed description of the procedure, refer to the i-STAT 1 System Manual.

Material Provided

i-STAT Total β-hCG cartridges

Materials Required but not Provided

i-STAT 1 Analyzer

02R29-01, 02R29-02, 02R29-03 i-STAT Total β-hCG Controls

05P59-04 i-STAT Total β-hCG Calibration Verification Material

Quality Control Procedures

On receipt of new cartridges, verify that the transit temperatures were satisfactory using the four-window temperature indicator strip included in the shipping container. For each lot of cartridges received, use a representative number of cartridges to analyze multiple levels of i-STAT Total β-hCG Controls for use on the i-STAT System using any verified i-STAT 1 Analyzer.* These controls should also be used to verify cartridge performance when storage conditions are in question.

*This is not a manufacturer's system instruction; it is a suggestion to comply with federal, state and local guidelines regarding quality control.

For additional information on Quality Control of the i-STAT System, refer to the 'Quality Control" section of the i-STAT 1 System Manual.

Proficiency Testing Recommendation

Proficiency Provider	Survey Title	Additional Information or Recommendations
College of American Pathologists (CAP) 325 Waukegan Road Northfield, IL 60093-2750 800-323-4040 or 847-832-7000 www.cap.org	CAP C Survey for General Chemistry and Therapeutic Drug Monitoring	The CAP C survey is a quantitative survey comprised of five liquid <u>serum</u> specimens. The only i-STAT cartridge that the C survey is recommended for is the i-STAT Total β-hCG cartridge.
	hCG, Serum (Immunology)	Qualitative/Quantitative Survey comprised of five liquid serum specimens.
American Proficiency Institute (API) 1159 Business Park Drive Traverse City, MI 49686 800-333-0958 www.api-pt.com	HCG, Quantitative: • Catalog #122 (5 serum samples) • Catalog #125 (5 serum samples)	For use with the i-STAT Total β-hCG cartridge.
WSLH Proficiency Testing (WSLH PT) 465 Henry Mall Room 402 Madison, WI 53706 800-462-5261 www.wslhpt.org	Chemistry/Endocrinology/ Therapeutic Drugs (CET) - 5 samples (PT01310)	For use with the i-STAT Total β-hCG cartridge only.

RESULTS

The test measures the hcg amount-of-substance concentration in plasma or the plasma fraction of whole blood (dimension IU/L) for *in vitro* diagnostic use.

Reportable Range

The i-STAT Total β-hCG test will report 5.0 IU/L to 2000.0 IU/L. Samples below the reportable range will display "<5.0 IU/L" on the handheld. Samples above the reportable range will display ">2000.0 IU/L" on the handheld.

Qualitative Interpretation of Results

The default setting on the handheld is a display of the quantitative β-hCG value as well as a qualitative interpretation of the β-hCG test result. The handheld can be customized to disable or enable the qualitative β-hCG interpretation.

Quantitative β-hCG Result	Qualitative β-hCG Interpretation	Handheld Display
< 5.0 IU/L	Negative	hCG QUAL (-)
5.0 – 25.0 IU/L	Indeterminate	hCG QUAL ( )
> 25.0 IU/L	Positive	hCG QUAL (+)

If enabled, qualitative interpretations will always be displayed with quantitative values.

LIMITATIONS OF THE PROCEDURE

The i-STAT Total β-hCG test is intended for use in the early detection of pregnancy only and should not be performed for any other purpose. For diagnostic purposes, hCG results should always be used in conjunction with other data, e.g., patient's medical history, symptoms, results of other tests, clinical impressions, etc. The i-STAT Total β-hCG test results should always be used and interpreted only in the context of the overall clinical picture.

End-users may obtain individual result > 15% negative bias for plasma samples when hCG concentrations are >5 IU/L.

Elevated hCG levels have been associated with some abnormal physiological states such as gestational trophoblastic disease and nontrophoblastic neoplasms.[2,3] Results of this test should not be used in the diagnosis of these abnormal states. Persistent low levels of hCG (e.g., <50 IU/L) may be present one to five years preceding malignant gestational trophoblastic disease.[4] There have been reports of people receiving unnecessary medical treatment and surgery, including chemotherapy and hysterectomy, when hCG results were used in the diagnosis of abnormal states.

Detection of low levels of hCG does not rule out pregnancy.[5] Because hCG values double approximately every 48 hours in a normal pregnancy,[5] patients with low levels of hCG should be resampled and retested after 48 hours.

Specimens from peri- or post-menopausal women may elicit weak positive results due to low hCG levels unrelated to pregnancy. With a weak positive result, it is good laboratory practice to resample and retest after 48 hours.

Because of the high degree of sensitivity of the test, positive results during the initial days after conception may later be negative due to natural termination of the pregnancy. Natural termination occurs in 22% of clinically unrecognized pregnancies and 31% of pregnancies overall.[6] It is good laboratory practice to resample and retest weak positive results after an additional 48 hours.

Interfering substances (such as heterophilic antibodies, non-specific proteins, or hCG-like substances) may falsely depress or falsely elevate results.[5,7,8] These interfering substances may cause false results over the entire range of the test, not just at low levels. While this product contains reagents that minimize the effect of these interferents and QC algorithms designed to detect their effects, the possibility of interference causing erroneous results should be evaluated carefully in cases where test results are inconsistent with clinical information. In these cases results should be confirmed by an alternate hCG method.[9]

Specimens from patients who have received preparations of mouse monoclonal antibodies for diagnosis or therapy may contain human anti-mouse antibodies (HAMA). Such specimens may demonstrate either falsely elevated or falsely depressed results when tested with test kits which employ mouse monoclonal antibodies.[10,11] These specimens should not be tested with the i-STAT Total β-hCG test.
Unknown interferences from medications may affect results.

Hook effect: No significant hook effect detected in samples up to 300,000 IU/L.

Partially clotted samples can result in elevated hCG results as well as quality check codes. To prevent clotting in samples collected in heparinized tubes, the sample should be inverted gently at least 10 times to ensure even dissolution of the heparin anticoagulant.

Grossly hemolyzed samples can cause a decreased alkaline phosphatase activity, resulting in decreased detection of hCG or quality check codes.

The i-STAT Total β-hCG test has been characterized in whole blood samples with hematocrit levels up to 55% PCV. Imprecision (CV) and bias exceeding 10% have been observed for samples with hematocrit levels above 50% PCV.

The handheld must remain on a level surface with the display facing up during testing. Motion of the handheld during testing can increase the frequency of suppressed results or quality check codes. A level surface includes running the handheld in the downloader/recharger.

The frequency of suppressed results is affected by atmospheric pressure. Suppressed result rates may increase with higher elevations (decreased barometric pressure) and may become persistent if testing is performed at more than 7500 feet (2286 meters) above sea level. Where unavailability of results is unacceptable, Abbott Point of Care recommends having an alternate test method available.

When testing whole blood, prior to filling the i-STAT Total β-hCG cartridge, invert the blood collection tube and inspect for red cell sedimentation. If sedimentation is observed, continue mixing by repeated inversion until the sedimentation is no longer apparent. Samples from β-hCG positive patients or patients undergoing hormone therapy may have higher erythrocyte sedimentation rates (ESR) which, if not tested immediately, could cause visible red cell sedimentation at the bottom of the collection tube.[12,13]

EXPECTED VALUES

Because hCG is normally synthesized and secreted by cells of the placenta or its precursor, levels of the hormone in normal, non-pregnant pre-menopausal individuals are low to undetectable.[14] Concentrations of hCG measured in the sera of non-pregnant individuals, as reported in the literature, are < 5 IU/L.[15,16,17,18]

Total β-hCG concentrations were measured in lithium heparinized blood and plasma samples collected from 123 apparently healthy non-pregnant females ≥ 18 and < 40 years, and 125 apparently healthy non-pregnant females > 40 years, using the i-STAT Total β-hCG test.

The median, range and 95th percentile with 95% confidence intervals for the two age groups were calculated. The median and range were also reported for the subjects ≥ 40 years based on menopausal status. Menopausal status was defined as 12 months since last menses and was self-reported by subjects. The observed results are presented below.

Reference Population age (years)	N Subjects	N Whole blood results	N Plasma results	Median (IU/L)	Range (IU/L)	95th Percentile (IU/L), [95% CI]
≥ 18 and < 40	123	122	120	0	0 – 3.9	0.7 [0.3, 1.6]
≥ 40 y	125	125	124	0	0 – 9.6	4.5 [4.0 , 5.4]
≥ 40 y, pre-menopausal	68	68	68	0	0 – 2.5	--
≥ 40 y post-menopausal	57	57	56	1.5	0 – 9.6	--

Each facility should establish it's own reference ranges to assure proper representation of specific populations.

The concentration of hCG rises rapidly during the first weeks of pregnancy, approximately doubling every two days. Therefore, values of total β-hCG between 5 IU/L and 25 IU/L may be indicative of early pregnancy.[19] However, these results must always be evaluated in the context of the clinical situation, the date of the last menstrual period, pelvic examination, and other clinical findings or diagnostic modalities[20] (see Limitations of Procedure section above). When borderline results between 5 IU/L and 25 IU/L are encountered, or β-hCG results do not match clinical context, re-test β-hCG 48 hours later.[19,21] Levels of hCG >25 IU/L are indicative of early pregnancy.[17] Values for hCG generally peak during the first trimester and decline slowly throughout the remainder of the pregnancy.

SPECIFIC PERFORMANCE CHARACTERISTICS

Precision

The i-STAT Total β-hCG test is designed to have total imprecision ≤ 10% CV for concentrations above 14 IU/L, or a standard deviation (SD) of 1.4 IU/L for concentrations ≤ 14 IU/L in blood and plasma. Two separate studies were each performed at the Point-of-Care. The first study, using hCG spiked blood, was performed at each of three sites . One of four target levels was prepared each day over four consecutive days, with a unique donor for each preparation. Seven analyzers were used per site, and three replicates were run per analyzer, per sample.

Results from each site are represented below.*

POC Site 1

Target Concentration	n	Min (IU/L)	Max (IU/L)	Mean (IU/L)	SD	SD, 95% CI	%CV	%CV, 95% CI
5 IU/L	21	3.9	6.5	5.2	0.81	0.62, 1.17	15.45	11.80, 22.38
25 IU/L	21	23.0	28.4	24.8	1.44	1.10, 2.08	5.80	4.43, 8.38
Mid range	21	804.1	1072.4	935.5	60.69	44.76, 94.22	6.49	4.79, 10.07
High range	21	1891.2	2323.1	2039.8	111.61	84.65, 163.84	5.47	4.15, 8.03

POC Site 2

Target Concentration	n	Min (IU/L)	Max (IU/L)	Mean (IU/L)	SD	SD, 95% CI	%CV	%CV, 95% CI
5 IU/L	21	4.3	5.6	5.0	0.39	0.30, 0.56	7.71	5.89, 11.14
25 IU/L	21	28.5	34.8	30.5	1.87	1.43, 2.71	6.14	4.69, 8.87
Mid range	21	866.5	1128.3	1008.1	55.65	41.72, 83.59	5.52	4.14, 8.29
High range	21	1474.3	1850.8	1641.0	105.81	80.02, 156.20	6.45	4.88, 9.52

POC Site 3

Target Concentration	n	Min (IU/L)	Max (IU/L)	Mean (IU/L)	SD	SD, 95% CI	%CV	%CV, 95% CI
5 IU/L	21	4.4	6.0	5.0	0.42	0.32, 0.61	8.51	6.48, 12.38
25 IU/L	21	25.0	32.6	27.9	1.97	1.41, 3.25	7.04	5.05, 11.65
Mid range	21	753.5	955.9	842.5	50.55	35.99, 84.79	6.00	4.27, 10.06
High range	21	1553.5	2064.4	1816.4	132.52	96.86, 209.70	7.30	5.33, 11.54

The second study using four levels of spiked plasma was performed over five days at three different sites. Five replicates of each level were tested on five analyzers at each site. Within-day and within-site imprecision are represented below.

Plasma Reproducibility at the Point-of-Care*

Target Concentration	n	Min	Max	Mean	Within-Day		Within-Site		Overall	
		IU/L	IU/L	IU/L	SD	%CV	SD	CV	SD	CV
5 IU/L	75	0.0	7.1	5.5	0.75	13.61	0.88	16.05	1.03	18.7
25 IU/L	75	21.9	27.2	24.3	1.26	5.16	1.26	5.16	1.26	5.18
Mid range	75	1038.5	1277.1	1155.7	49.76	4.31	50.77	4.39	53.08	4.59
High range	75	1636.1	2249.8	1874.5	104.95	5.60	104.95	5.60	111.11	5.93

* Representative data; results in individual laboratories may vary from these data.

Method Comparison

Quantitative

Method comparison data were collected using CLSI guideline EP9-A2.[22] Blood samples were collected at the point-of-care at four external clinical sites in heparinized evacuated tubes and analyzed in duplicate on the i-STAT System. The blood collection tubes were sent to the laboratory and the plasma portion was separated from the red cells. The plasma portion was tested in duplicate on both the i-STAT System and the ARCHITECT system.

A weighted Deming regression analysis was performed using the first replicate result from each sample. In the method comparison table, n is the number of specimens in the first data set, and Sxx and Syy refer to estimates of imprecision based on the duplicates of the comparative and the i-STAT methods respectively. Sy.x is the standard error of the estimate, and r is the correlation coefficient.

Method comparison results will vary from site to site due to differences in sample handling, comparative method calibration and other site specific variables.

Quantitative Method Comparison: i-STAT vs Abbott Architect (IU/L)

	i-STAT (Whole Blood) vs ARCHITECT (Fresh Plasma)	i-STAT (Fresh Plasma) vs ARCHITECT (Fresh Plasma)
n	134	134
Slope	0.95	1.02
Intercept	2.39	-0.22
Sy.x	0.131	0.105
Syy	7.3%	5.4%
Sxx	3.2%	3.2%
r	0.99	0.99
Xmin	8.2	6.3
Xmax	1624.4	1948.8

Qualitative

Qualitative results from clinical samples gathered in the method comparison studies were analyzed for concordance with the Abbott Architect. Samples producing results below 5.0 IU/L or above 2000.0 IU/L were included in the data set.

Qualitative Method Comparison: i-STAT Whole Blood vs Abbott ARCHITECT

		Architect plasma			
		Positive	Indeterminate	Negative	Total
i-STAT whole blood	Positive	188	1**	0	189
	Indeterminate	0	12	2**	14
	Negative	0	1**	108	109
	Total	188	14	110	312

Qualitative Method Comparison: i-STAT Plasma vs Abbott ARCHITECT

		Architect plasma			
		Positive	Indeterminate	Negative	Total
i-STAT plasma	Positive	188	0	0	188
	Indeterminate	1**	13	2**	16
	Negative	0	1**	108	109
	Total	189	14	110	313

**Quantitative Values (IU/L) of Discordant Points

Blood	
i-STAT	Architect
5.8	4.89
5.3	4.84
< 5.0	5.78
26.0	24.44
Plasma	
i-STAT	Architect
6.2	4.89
5.2	4.84
< 5.0	5.78
24.2	28.85

Analytical Specificity

The i-STAT Total β-hCG test is specific for the β subunit (free and intact) of hCG. The following were tested and found to have an insignificant effect on the measured β-hCG.

Crossreactant	Concentration	Crossreactivity (%)
LH	450 IU/L	< 10%
FSH	300 IU/L	< 10%
TSH	100 mIU/L	< 10%

Limit of Quantitation, Limit of Detection, Limit of Blank

The Limit of Quantitation (LOQ), Limit of Detection (LOD), and Limit of Blank (LOB) were all estimated (as per CLSI guideline EP17-A[23]) to be below the lower end of the reportable range, 5 IU/L.

Recovery

A dilution recovery study was performed using heparinized whole blood and plasma samples from six donors. For each donor, the original negative sample and β-hCG spiked samples were prepared with WHO 5th IS (07/364) in either heparinized whole blood or heparinized plasma to approximately 2000 IU/L. The spiked samples were diluted using unspiked whole blood or plasma and tested in a minimum of ten cartridges. A series of nine levels were generated for each donor. For samples with hcg concentrations >5 IU/L, the individual recovery results for whole blood ranged from 91.1% to 118.5%, and for plasma samples from 81.8% to 103.3% when compared to WHO hCG 5th IS. For whole blood samples with hCG at a concentration of ~5 IU/L, the individual bias ranged from 0.3 to 1.1 IU/L, and for plasma samples from -0.2 to -1.2 IU/L when compared to WHO hCG 5th IS. End-users may obtain individual result > 15% negative bias for plasma samples when hCG concentrations are >5 IU/L.

Percent recovery results were pooled across each hCG concentration.

Summary Recovery Performance, Whole Blood

Level	Expected Mean (IU/L)	Observed Mean (IU/L)	% Recovery or Absolute Bias
1	1936.4	1974.6	102.0 %
2	972.7	989.3	101.7 %
3	644.8	677.4	105.1 %
4	484.2	509.5	105.2 %
5	242.2	261.4	107.9 %
6	121.3	128.2	105.7 %
7	60.6	62.9	103.8 %
8	24.3	26.6	109.5 %
9	5.1	5.8	0.7 IU/L

Summary Recovery Performance, Plasma

Level	Expected Mean (IU/L)	Observed Mean (IU/L)	% Recovery or Absolute Bias
1	1972.6	1811.5	91.8 %
2	986.5	895.5	90.8 %
3	657.5	622.1	94.6 %
4	493.3	475.0	96.3 %
5	246.9	234.1	94.8 %
6	123.5	109.2	88.4 %
7	61.8	54.5	88.2 %
8	24.8	22.6	91.0 %
9	5.3	4.5	0.8 IU/L

Interference Testing

Interference studies were based on CLSI guideline EP7-A2.[24] The following substances were found to have no significant effect (less than 10%) on the i-STAT Total β-hCG test when added to a plasma pool containing approximately 40 IU/L of β-hCG, at the concentrations indicated:

Compound	Test Level (µmol/L unless otherwise indicated)
Acetyl Salicylic Acid	3620
Acetaminophen	1660
Albumin	60 g/L
Allopurinol	294
Ampicillin	152
Ascorbic Acid	342
Atenolol	37.6
Bilirubin	342
Caffeine	308
Captopril	23
Chloramphenicol	155
Cholesterol	13 mmol/L
Diclofenac	169
Digoxin	6.53
Dopamine	5.87
Enalaprilat	0.86
Erythromycin	81.6
Furosemide	181
Hemoglobin	2 g/L
Ibuprofen	2425
Isosorbide dinitrate	636
Triglycerides	37 mmol/L
Nicotine	6.2
Nifedipine	1156
Phenytoin	198
Propranolol	7.71
Salicylic acid	4340
Sodium Heparin	90 U/mL
Theophylline	222
Uric Acid	1.4 mmol/L
Verapamil	4.4
Warfarin	65.2

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Abbott Point of Care Inc.
100 and 200 Abbott Park Road
Abbott Park, IL 60064 • USA

EC REP

Emergo Europe
Molenstraat 15
2513 BH, The Hague
The Netherlands

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i-STAT® TECHNICAL BULLETIN

NEW ULTRALIFE 9-VOLT LITHIUM BATTERY FOR USE WITH THE i-STAT SYSTEM

NEW
Ultralife 9-Volt
Lithium Battery
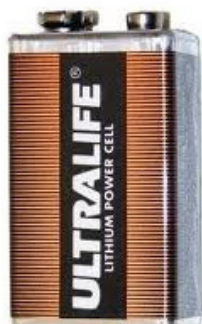
CURRENT
Ultralife 9-Volt
Lithium Battery

1. OVERVIEW

Ultralife Battery and Energy Products, the manufacturer of the current 9-volt lithium battery (Part No. U9VL-J) sold by Abbott Point of Care (APOC) for use with the i-STAT System is releasing a new 9-volt lithium battery (Part No. U9VL-J-P), which will replace the current U9VL-J battery for shipment to i-STAT customers.

This Technical Bulletin describes general notes and considerations regarding ordering and use of the new Ultralife 9-volt lithium battery.

Note: The new Ultralife 9-volt lithium battery has a safety feature that provides protection preventing the i-STAT handheld from overheating due to component failure within the analyzer circuitry.

2. GENERAL NOTES AND CONSIDERATIONS

1. The new Ultralife 9-volt lithium battery has the same Abbott List Number as the current battery – 06F21-26. The new battery will also be packaged the same as the current battery, with each box containing 6 batteries.

2. The new batteries are installed and removed using the same procedure as the current battery. Instructions for removal and replacement can be found in Section 17 of the i-STAT 1 System Manual: *Routine Care of the Analyzer and Downloader* or Section 2 of the i-STAT System Manual: *Portable Clinical Analyzer.*

3. The capacity for the new Ultralife 9-volt lithium battery is the same as the current battery. Information regarding the expected lifetime for a pair of lithium batteries can be found in the Disposable Batteries paragraph in Section 2 of the i-STAT 1 System Manual: *i-STAT 1 Analyzer.* or in the *Power* paragraph in Section 2 of the i-STAT System Manual: *Portable Clinical Analyzer.*

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i-STAT® TECHNICAL BULLETIN

Proficiency Testing on the i-STAT System

Please read this Technical Bulletin in its entirety before participating in a Proficiency Testing (PT) event as there are reminders and helpful information to enhance your probability of successful performance. Pay special attention to the "Coding i-STAT Results" section since coding information may change periodically.

Proficiency testing provides a snapshot in time of the analytic performance for a given test. The use of inter-laboratory comparison, provided by PT, allows laboratories to ensure that their instruments are performing at a level comparable to their peers. Peer performance is enhanced by following the instructions of the manufacturer.

CLIA REQUIREMENTS FOR PROFICIENCY TESTING

Moderate Complexity Tests

CLIA regulation *Subpart H – Participation in Proficiency Testing* requires a laboratory to enroll in a proficiency testing program approved by the Centers for Medicare and Medicaid Services (CMS) for its primary test system or that system used at its primary site. The laboratory must participate successfully as defined by the criteria defined in *Subpart I – Proficiency Testing Programs*.

A primary testing system is defined as the only method or the primary method for performing and reporting tests under a CLIA certificate. The i-STAT System may be a primary testing system when:

- A hospital has separate CLIA certificates for the main laboratory and point of care testing;

- A hospital owns a clinic, same-day surgery, kidney dialysis unit, etc., which requires a separate CLIA certificate;

- The i-STAT System is the hospital's primary laboratory testing system; or

- The i-STAT System is the main testing system in a physician's office, skilled nursing facility, unaffiliated patient transport service, home healthcare agency, etc.

For CLIA regulated analytes, proficiency testing (PT) programs must provide three separate shipments during the year that include five challenges for each analyte or test. Laboratories must comply with the CLIA requirements and those of their accrediting organization when testing PT samples.

Waived Tests

Proficiency Testing for waived tests is not a CLIA requirement nor is it a requirement from The Joint Commission. COLA recommends PT testing and will issue an educational citation for noncompliance. The College of American Pathologists (CAP) requires proficiency testing for waived tests. Check with your state regulatory agency for state requirements.

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With the i-STAT 1 System, the FDA has categorized the tests included on the i-STAT G, Crea, E3+, EC4+, 6+, and CHEM8+ cartridges as waived when testing is performed using venous whole blood samples collected in sodium or lithium heparin evacuated tubes. Other venous whole blood samples, capillary, and/or arterial samples tested using these same cartridges on the i-STAT 1 System are categorized by the FDA as moderate complexity.

CODING i-STAT RESULTS

Proficiency Testing providers use different methods for coding results. The information below should be used to select the correct code(s).

Periodically, Abbott Point of Care (APOC) makes cartridge manufacturing changes which may affect the results for non whole-blood samples, such as proficiency testing (PT) material. Cartridge generations are identified by the prefix letter preceeding the cartridge lot number.

<u>Miscoding your results can cause PT failures. Continued PT failures may result in the loss of your permission to report results. Furthermore, miscoding may cause inaccurate peer group means, resulting in unnecessary failures for some participants.</u>

APOC recognizes that it may be difficult for PT providers and customers to ensure proper coding. We are working with the PT providers to prevent unnecessary PT failures and will continue to work with customers and providers when we suspect failures are due to miscoding or inappropriate peer groups. **Therefore, it is important for troubleshooting purposes to record the cartridge type and lot number used to report PT results.**

Note 1: pH and PCO$_2$ results from EC8+ cartridge lots with prefix letters F, G, H, J, and K will not agree with pH and PCO$_2$ results from other cartridges. When reporting results, look for a separate peer group for these cartridge lots.

Note 2: For creatinine results, select IDMS-Traceable Calibration, if available. If not available, make your selection based upon the cartridge type and lot number.

Note 3: When reporting results with the < or > symbol, you must record the lowest or highest reportable value. Make sure the symbol is legible and cannot be interpreted as a number. For CAP participants, fill in the <\> bubble.

Follow the proficiency testing survey instructions for reporting results. Double check the coding as well as the CLIA number, test results, and any additional information required before submitting result forms to your provider. **<u>Record and retain the cartridge type and lot number used to test samples.</u>** If you have any questions, contact your provider or APOC Technical Support at 1-800-366-8020, option 1.

USE THE PROFICIENCY TEST PATHWAY

It is recommended that the Proficiency Test path be used on the i-STAT 1 Analyzer when testing proficiency samples, especially those that include hematocrit or ACT. The Proficiency Test path uses K$_3$EDTA standardization coefficients for hematocrit and disables the CPB mode. It also uses the PREWARM mode for ACT. Use of the Proficiency Test path will ensure that the results from analyzers customized for K$_2$EDTA, CPB-Always, or ACT NONWARM will match results from analyzers customized for K$_3$EDTA, CPB-Never and ACT PREWARM for survey reporting purposes. If the patient sample test path is used instead of the Proficiency Test path, do not select CPB, and if the analyzer is customized for K$_2$EDTA, divide the hematocrit results by 1.0425 before reporting. There is no reliable way of converting NONWARM ACT results to PREWARM ACT results.

- To access the Proficiency Test path on the i-STAT 1 Analyzer

     1. Press the On/Off key.
     2. Press the MENU key.
     3. Press 3 for Quality Tests.
     4. Press 2 for Proficiency.

SAMPLE HANDLING

It is especially important not to expose aqueous samples for blood gases and ionized calcium to air. The instructions in the Quality Control section of the i-STAT System Manual under "Transfer with Capillary Tube" or "Transfer with Syringe" should be followed.

- Take care not to draw air bubbles into the transfer device. If there is only one ampule per level, the opened ampule may be exposed to air for too long to fill a second transfer device. Exposure to air could affect pH, PCO2, PO2 and ionized calcium results.
- If air is trapped between the leading edge of the solution and the syringe plunger, do not invert the syringe to expel it. Air trapped near the plunger will not affect results from the solution near the tip of the syringe, but may affect the sample as it passes through the syringe when being expelled.
- One or two drops should be expelled from a syringe before filling a cartridge.

PROFICIENCY TEST FAILURES

Certain PT survey samples are not compatible with i-STAT System sensors and may contain interfering substances that could affect results. Fluorocarbon samples for blood gases and fixed-cell samples for hematocrit are not compatible with the sensors.

Occasionally, results from non-whole blood samples may differ between older and newer generations of cartridges. These differences may be significant. Abbott Point of Care will work with PT providers to prevent i-STAT System users from being unfairly penalized for PT failures that can be attributed to manufacturing changes. This is why it is important to record the cartridge type and lot numbers used to test samples. Note: the CLEW software prevents manufacturing changes from affecting results when testing patient samples.

PROFICIENCY TESTING SURVEY PROVIDERS

Note 1: This list may not include all providers and is not intended as an endorsement of any particular provider. Abbott Point of Care no longer evaluates surveys and assumes that for those surveys that list the i-STAT System, compatibility has been confirmed by third-party testing or a history of adequate results.

Note 2: Select a Proficiency test for hematocrit which is formulated for a conductometric method

Proficiency Provider	Proficiency Title(s)	Additional Information or Recommendations
College of American Pathologists (CAP)		
College of American Pathologists (CAP) 325 Waukegan Road Northfield, IL 60093-2750 800-323-4040 or 847-832-7000 www.cap.org	CAP AQI AQ3 Survey for blood gases and electrolytes: includes iCa, Cl, Hct, Hb, Lac, PCO$_2$, pH, PO$_2$, K, Na, and TCO$_2$ CAP AQI AQ4 Survey for blood gases and electrolytes: includes all AQ3 analytes plus Glu, BUN, and Crea. Note: CAP does not include measured TCO$_2$ as a reportable value for AQI AQ3/AQ4 surveys.	PO2 results should not be corrected for barometric pressure.
	CAP CT5 Survey for Activated Clotting Time (ACT)	Samples are reconstituted with calcium chloride **supplied by CAP.**
	CAP Plasma Cardiac Markers (PCARM) Survey	For use with i-STAT cTnI, CK-MB, and BNP cartridges.
	Whole Blood PT/INR (WP3)	

Proficiency Provider	Proficiency Title(s)	Additional Information or Recommendations
(CAP) continued	CAP C Survey for General Chemistry and Therapeutic Drug Monitoring	The CAP C Survey is a quantitative survey comprised of five liquid serum specimens. The only i-STAT cartridge that the C Survey is recommended for is the i-STAT Total ß-hCG cartridge.
	hCG, Serum (Immunology)	Qualitative/Quantitative Survey comprised of five liquid serum specimens.
American Association of Bioanalysts (AAB)		
American Association of Bioanalysts (AAB) AAB Proficiency Testing Service 205 West Levee St. Brownsville, Texas 78520 800-234-5315 www.aab-pts.org	Activated Clotting Time (2009203) - (2 samples)	
	Whole Blood Prothrombin Time (2009223) - (5 samples)	
	Chemistry, i-STAT (1009933) - (5 samples) Chemistry, i-STAT, Waived (1001155) - (2 samples)	
American Proficiency Institute (API)		
American Proficiency Institute (API) 1159 Business Park Drive Traverse City, MI 49686 800-333-0958 www.api-pt.com	i-STAT Chemistry (including Blood Gases) - Catalog #145 (5 samples) - Catalog #A45 – Verification Program (5 samples) - Catalog #945 – Waived (2 samples) - Catalog #J45 – Waived, Verification Program (2 samples)	
	i-STAT ACT (Activated Clotting Time) - Catalog #215 (2 samples) - Catalog #B15 –Verification Program (2 samples)	Calcium Chloride is included to reconstitute the samples.
	i-STAT Protime/INR - Catalog #216 (5 samples) - Catalog #B16 – Verification Program (5 samples)	Calcium Chloride is included to reconstitute the samples.
	Cardiac Markers - Catalog #140 (5 samples) - Catalog #A40 – Verification Program (5 samples) - Catalog #920 (2 samples) - Catalog #J20 – Verification Program (2 samples)	For use with i-STAT cTnI, CK-MB, and BNP cartridges. If additional sample is required for testing multiple cartridge types, please add on #165.
	HCG, Quantitative - Catalog #122 (5 samples) - Catalog #125 (5 samples)	For use with the i-STAT Total ß-hCG cartridge.

Proficiency Provider	Proficiency Title(s)	Additional Information or Recommendations
WSLH PT		
WSLH Proficiency Testing (WSLH PT) 465 Henry Mall Room 402 Madison, WI 53706 800-462-5261 www.wslhpt.org	Activated Clotting Time (PT2030)	
	Blood Gases / Electrolytes / Metabolites (PT01050) Blood Gases / Hemoglobin / Hematocrit (PT01570)	
	Electrolytes / Metabolites/ Hemoglobin / Hematocrit – Waived Methods (PT01400)	
	Protime/INR – Whole Blood (PT02370)	
	Cardiac Assessment – 5 samples (PT01260) Cardiac Assessment – 3 samples (PT01230)	For use with i-STAT cTnI cartridges only.
	Chemistry / Endocrinology / Therapeutic Drugs (CET) – 5 samples (PT01310)	For use with i-STAT Total β-hCG cartridges only.
California Thoracic Society		
California Thoracic Society 575 Market St. Suite 2125 San Francisco, CA 94105 415-536-0287 www.calthoracic.org	ABG - Electrolytes + Blood Gas/Hemoglobin/Hematocrit	
AccuTest Inc. and Oneworld Accuracy Canada		
AccuTest Inc. P.O. Box 999 7 Hayrick Lane Westford, MA 01886-0031 800-665-2575 oneworldaccuracy.com Oneworld Accuracy Canada (Canada Only) 9-8980 Fraserwood Court Burnaby, BC V5J 5H7 Canada 800-665-2575 oneworldaccuracy.com	i-STAT Blood Gas / Electrolytes / Hematocrit: IBGH435 (5 samples) & IBGH432 (2 samples - for waived testing.) Cardiac Markers CARM432 (2 Samples) CARM435 (5 Samples)	Includes pH, $P\text{CO}_2$, $P\text{O}_2$, Na, K, Cl, $T\text{CO}_2$, Glu, Lac, iCa, Crea, Urea, Hct, Hgb Calc. For waived testing, order IBGH432. Includes Cardiac Troponin I (cTnI) and BNP.

Proficiency Provider	Proficiency Title(s)	Additional Information or Recommendations
American College of Physicians - Medical Laboratory Evaluation (MLE)		
ACP-Medical Laboratory Evaluation (MLE) 25 Massachusettes Ave., NW Suite 700 Washington, DC 20001-7401 800-338-2746, option 5 www.acponline.org/mle email: mle@acponline.org	i-STAT Chemistry 1 - Catalog #817 (includes #818 & 847)	
	i-STAT Chemistry 2 - Catalog #818 (5 samples)	Includes Cl, TCO_2, Crea, Glu, Hct, Hb, iCa, K, Na, and BUN.
	i-STAT Chemistry -Waived - Catalog #832 (Same as #818 above, but with 2 samples per shipment)	
	Blood Gases - Catalog #847	Includes Cl, iCa, PCO_2, pH, PO_2, K, and Na.
	i-STAT Protrombin Time/INR - Catalog #328	
American Academy of Family Physicians - Proficiency Testing Program (AAFP - PT)		
American Academy of Family Physicians Proficiency Testing Program (AAFP-PT) 11400 Tomahawk Creek Parkway Leawood, Kansas 66211-2672 800-274-7911 www.aafp.org/pt email: pt@aafp.org	Module 700 - i-STAT Chemistry - (5 specimens)	For G, Crea, E3+, EC4+, CHEM8+, and 6+ cartridges.
	Module 721 - i-STAT Chemistry/Blood Gas Combo - (5 specimens)	For all cartridges listed for Module 700 plus EG6+, EG7+, CG8+, and EC8+.
	Module 722 - i-STAT Chemistry-Waived - (1 specimen)	For CHEM8+, 6+, EC4+, E3+, G, and Crea cartridges.
	Module 723 - i-STAT Blood Gases - (5 specimens)	For G3+ and CG4+ cartridges.
	Module 748 - i-STAT Protime/INR	

Art: 714262-00AG   Rev. Date: 03-Mar-17

i-STAT® TECHNICAL BULLETIN

REPLACING THE NiMH RECHARGEABLE BATTERY IN THE MARTEL PRINTER USED WITH THE i-STAT®1 ANALYZER

⚠️ **Prior to starting, assure the printer is disconnected from the AC Power Adapter. Installing the Battery Pack Connector backwards can cause the printer to overheat. Follow the instructions in this Bulletin to prevent damage.**

Background

The NiMH rechargeable battery contained in the Martel Printers can be replaced if the printer has a battery door. Refer to Figure 1 in Appendix.

Procedure

1. Disconnect the printer from the AC Power Adapter.

2. Turn the Martel Printer upside down and place it on a flat surface. Remove the battery door by sliding it off while pressing on the grooved arrow. Set the door aside. Refer to Figures 2 and 3 in Appendix.

3. Disconnect the existing battery by gently pulling up on the red/black wires until the connector releases from the two metal pins. Once the battery is disconnected, remove it completely from the battery compartment.

4. Remove the new rechargeable battery from its packaging. With the thumb and index finger of one hand, grasp the connector at the end of the red/black battery wires.

5. Assure proper connector alignment as shown. See Figure 4 below. For alternate connector location, refer to Figure 7 in Appendix.

Connector

Alignment Tab

Assure proper connector alignment as shown.

Figure 4

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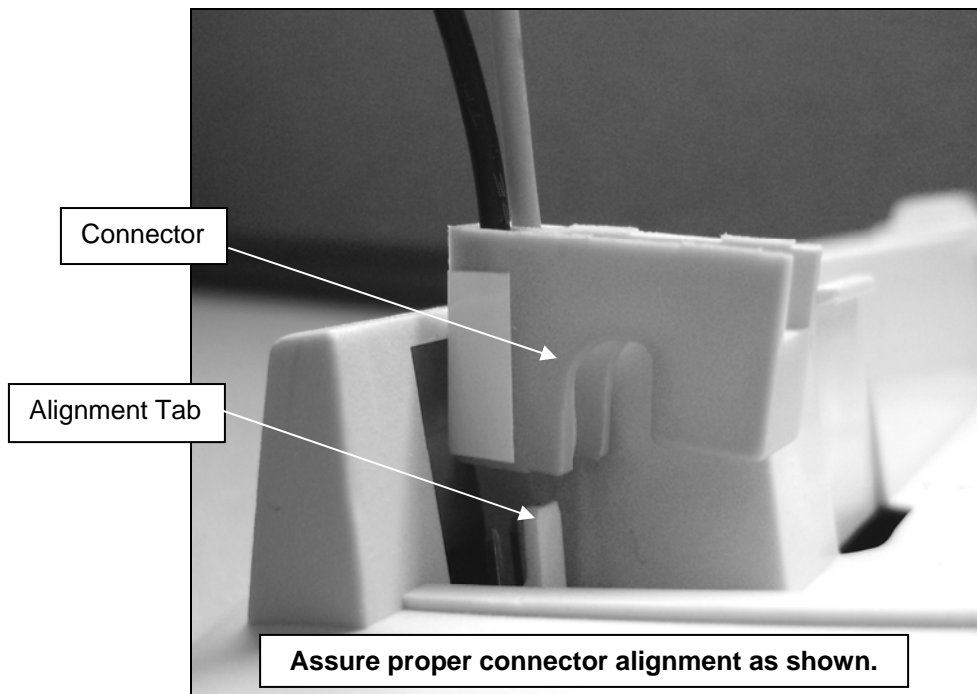
6. Slide the connector onto the two metal connector pins behind the alignment tab on the printer. Refer to Figures 5 and 6 in Appendix.

7. Once the wires are connected, place the battery portion of the pack into the rectangular compartment. Make sure the wires are not under the battery or projecting out of the opening.

8. Slide the battery door back onto the compartment until it closes and locks into place.

9. Turn the printer over, plug it back into the AC power adapter, and charge the new battery in the printer for a minimum of 9 hours before use (fast charging occurs only when the printer is turned off).

Symptoms Indicating that the NiMH Rechargeable Battery Requires Replacement

1. A steady yellow Status Light on the printer, even after charging it for the recommended 9 hours.

2. Loss of battery capacity, indicated by a shorter interval between charges.

3. The printer Power LED does not come on when the printer is turned on. The power adapter cannot supply sufficient power for printing so the battery needs to be partially charged before printing is possible.

Procedure for Ordering a Replacement NiMH Rechargeable Battery

To order a replacement NiMH rechargeable battery, call Abbott Customer Service at 1-800-323-9100. The Abbott list number for the NiMH rechargeable battery is 06F21-35.

Appendix

| Figure 1 | Figure 2 | Figure 3 |

| Figure 5 | Figure 6 | Figure 7 |
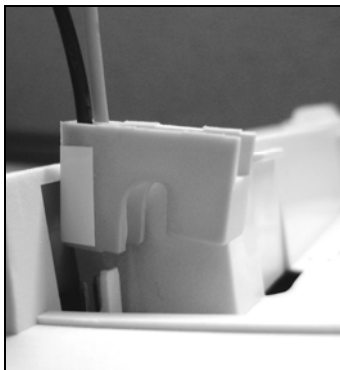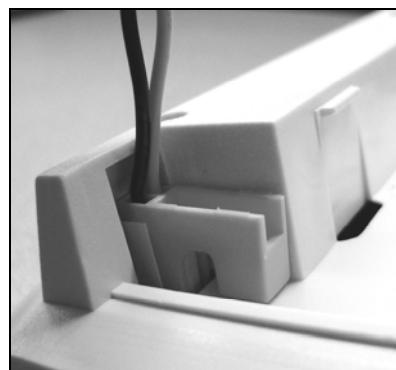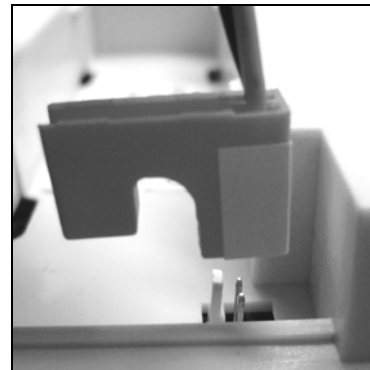
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i-STAT® TECHNICAL BULLETIN

Instructions For Restoring Analyzers That Produce *** For Hematocrit and Quality Check Code 23

Hematocrit star-out (***) results and Quality Check Code 23 may be reduced by restoring an analyzer with the reusable i-STAT Ceramic Conditioning Cartridge. This technical bulletin contains instructions for this restoration process.

QUICK REFERENCE

Using an i-STAT Ceramic Conditioning Cartridge (CCC)

Step	Action
1	Run an external Electronic Simulator
2	Run the CCC two times
3	Update the CCC Usage Log
4	Return the analyzer to service

DETAILED INSTRUCTIONS

Using an i-STAT Ceramic Conditioning Cartridge (CCC)

1.   ***Run an external Electronic Simulator***

If the analyzer is configured with the Internal Electronic Simulator enabled, run an external Electronic Simulator. Running the external Electronic Simulator ensures the Internal Simulator cycle will not execute during the restoration cycle, which could lead to the premature termination of restoration cycle.

2.   ***Run the CCC two times***

Initiate the CCC cycle as you would initiate an external Electronic Simulator cycle. The instrument will identify the CCC as an external Electronic Simulator and display a Simulator Failure Code (i.e: rRGL) when the cycle is complete. Disregard the code, as this is expected behavior.

3.   ***Update the CCC Usage Log***

Update the CCC Usage Log to keep track of the number of restoration cycles performed with the current ceramic strip in the CCC. If necessary, replace or rotate the ceramic strip so the CCC is ready for future use. Refer to sections below for the CCC Usage Log and maintenance instructions.

4.   ***Return the analyzer to service***

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Ceramic Conditioning Cartridge Usage Log

Ceramic Cartridge Serial Number[1] _____

NEW STRIP

Check one box for each time the ceramic cartridge is run in the analyzer. Typically, this means two boxes are checked each time an analyzer is restored with the ceramic cartridge (serial number shown above).

There are 50 boxes. If the strip is damaged[2], replace the strip, start a new log. After all the boxes immediately below are checked, rotate the strip as instructed and continue to check-off boxes for each analyzer restoration.

FIRST ROTATION

Rotate the strip 180 degrees, keeping the same side up.

Check one box for each time the ceramic cartridge is run in the analyzer. Typically, this means two boxes are checked each time an analyzer is restored with the ceramic cartridge (serial number shown above).

There are 50 boxes. If the strip is damaged[2], replace the strip, start a new log. After all the boxes immediately below are checked, rotate the strip as instructed and continue to check-off boxes for each analyzer repair.

SECOND ROTATION

Flip the strip over, so the bottom side is now up.

Check one box for each time the ceramic cartridge is run in the analyzer. Typically, this means two boxes are checked each time an analyzer is restored with the ceramic cartridge (serial number shown above).

There are 50 boxes. If the strip is damaged[2], replace the strip, start a new log. After all the boxes immediately below are checked, rotate the strip as instructed and continue to check-off boxes for each analyzer repair.

THIRD AND LAST ROTATION

Rotate the strip 180 degrees, keeping the same side up.

Check one box for each time the ceramic cartridge is run in the analyzer. Typically, this means two boxes are checked each time an analyzer is restored with the ceramic cartridge (serial number shown above).

There are 50 boxes. If the strip is damaged[2], replace the strip, start a new log. After all the boxes are checked, discard the strip as instructed below.

DISCARD STRIP

Replace the strip with a new strip, and start a new log

[1] Serial Number is etched on the cartridge base.

[2] Inspect the ceramic cartridge for damage. Check to make sure the ceramic strip is centered (i.e., is not hanging over either edge), that the screw is secure, and that the ceramic is not chipped or cracked. Wear marks (appearing as small lines on the ceramic) are normal.

Art: 721215-00B Rev. Date: 10-Jun-11

MAINTAINING THE CERAMIC CONDITIONING CARTRIDGE

The Ceramic Conditioning Cartridge consists of an aluminum base that supports a ceramic "strip." The strip is a white strip of Alumina that is held down by a brass retainer and retainer screw. The ceramic cartridge may be used up to 50 times before the strip is worn and needs to be rotated or up to 200 times before the strip must be replaced as described below.

Request replacement parts by contacting your i-STAT support provider and refer to the following i-STAT part numbers:

Description	List/Part Number
Ceramic Cartridge, Packaged (with box, spare strips, etc.)	04J51-01
User Guide, Ceramic Cartridge	014540-01
Ceramic Cartridge (Cartridge only)	014499-01
Ceramic Strip	014542-01
Screw	014543-01
Retainer (brass plate with hole in it)	014544-01
Base (Aluminum support shaped like cartridge)	014545-01

PROCEDURE FOR ROTATING THE STRIP

Note: Rubber gloves should be worn to perform the following procedure.

1. Using a small Phillips head screwdriver, loosen and remove the screw and retainer.

2. Remove the ceramic strip.

   Note: The ceramic strip is brittle and should be handled with care to avoid damaging or contaminating it.

3. Inspect the ceramic strip for damage. Replace if cracked or chipped. CRACKED STRIPS MUST BE REPLACED BEFORE USING THE CERAMIC CARTRIDGE IN AN ANALYZER.

4. Inspect the aluminum base. Clean if necessary with isopropyl alcohol and soft, lint-free cloth. Avoid using paper that might leave fibers on the ceramic cartridge which might be carried into the analyzer.

5. Rotate the ceramic strip to the next orientation (either spin around or flip over).

   Note: The ceramic cartridge may be used to perform 25 repairs before rotating or replacing the strip. The strip may be rotated 3 times before replacing it (i.e., the strip has a total of 4 positions; original position of the strip plus 3 rotations). In other words, a single strip may be used to repair 100 analyzers – 25 analyzers per orientation of the strip. The 4 orientations are:

   1. Initial position
   2. The strip rotated by "spinning it" 180 degrees, same side up.
   3. The strip rotated by turning it over, now back-side up.
   4. The strip rotated by "spinning it" again 180 degrees, back-side still up.

6. Place the ceramic strip in the base, making sure it sits flat in the recess and does not overhang either edge (i.e., the inner edges adjacent to the strip, not the wider edges back on the body of the cartridge).

7. Replace the retainer plate and retainer screw.

   Note: Over-tightening the screw may damage the threads in the base or crack the ceramic strip.

8. Record the strip rotation in the Use Log.

PROCEDURE FOR REPLACING THE STRIP

Follow the same procedure as rotating the strip, except discard the old strip and insert a new strip in its place.

i-STAT® TECHNICAL BULLETIN

Hematocrit Determination in the i-STAT® System and Comparison To Other Methods

This bulletin describes the four most common methods for determining hematocrit (microhematocrit, conductometric, and as calculated by automated cell counters and co-oximeters) and the common interferences, which lead to discrepancies among the four methods.

The i-STAT System uses the conductivity method to determine hematocrit. The Point-of-Care Testing Coordinator should ensure that end users are aware of factors affecting results obtained on the i-STAT System. Factors affecting hematocrit results are included in this Technical Bulletin.

HEMATOCRIT

CLSI recommends that the term hematocrit be used to describe the materials and/or method used to measure Packed Cell Volume (PCV).[1] PCV is defined as the measure of the ratio of the volume occupied by the red cells to the volume of whole blood in a sample of capillary, arterial or venous blood. This ratio is measured after appropriate centrifugation and is formally expressed as a decimal fraction.

Abbott Point of Care Inc. has retained the term hematocrit for the measured quantity and, according to common practice, expresses hematocrit as a percentage, in units of Percent Packed Cell Volume (%PCV). A hematocrit of 0.45 PCV is expressed as 45 %PCV.

THE METHODS

The Microhematocrit Method

Microhematocrit is the standard method for hematocrit determination[1]. An anticoagulated sample in a microcapillary tube is spun in a centrifuge. The red blood cells are separated from the plasma by the centrifugal force. The height of the separated red blood cell column is compared to the height of the entire sample column to determine the packed cell fraction (*i.e.*, the hematocrit).

The hematocrit of a sample can be altered by the anticoagulant. It is well documented that K_3EDTA causes the cells to shrink by increasing the osmotic pressure in the plasma[1,2,3,4], thus reducing the hematocrit below its value *in-vivo*. Current literature indicates that the hematocrit is reduced between 1.5 %PCV and 2.2 %PCV at normal hematocrit levels. Experiments conducted by Abbott Point of Care Inc. indicate a shrinkage of about 2 %PCV at normal hematocrit levels. For more information, please see the Technical Bulletin "K_2EDTA and K_3EDTA Customization for Hematocrit on the i-STAT System" (716240).

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Conductivity Methods

Systems using the conductivity method, such as the i-STAT System, measure the electrical conductance of a whole blood sample. Plasma conducts electrical current, and blood cells act as insulators. A sample with a relatively high hematocrit has, by definition, a larger proportion of its volume filled by the non-conductive red blood cells. The overall conductance of the sample will thus be relatively low. In the i-STAT System, before the measured sample conductance is converted into a hematocrit value, corrections are applied for the temperature of the sample, the size of the fluid segment being measured, and the relative conductivity of the plasma component. The first two corrections are determined from the measured value of the calibrant conductance; the last correction is determined from the measured concentrations of sodium and potassium in the sample.

i-STAT provides two customization settings for reporting hematocrit results: The "K_3EDTA" customization reports hematocrit results traceable to MH-K_3EDTA. The "K_2EDTA" customization reports hematocrit results traceable to MH-K_2EDTA.

For best agreement of i-STAT and hematology analyzer hematocrit results, the i-STAT customization setting is selected according to the calibration of the comparative hematology analyzer (MH-K_2EDTA or MH-K_3EDTA).

When this Technical Bulletin was first released, the manufacturers of the Advia®, Cell-Dyn®, Coulter®, and Sysmex®, hematology analyzers used samples collected in K_3EDTA for the purpose of calibrating their systems to reference methods. The manufacturers of Advia, Cell-Dyn and Sysmex now use samples collected in K_2EDTA for the purpose of calibrating their systems to reference methods. Therefore, for best agreement between these analyzers and the i-STAT System, the K_2EDTA customization setting should be selected. (Note: The default setting on the i-STAT System is K_3EDTA.)

Automated Hematology Analyzer Methods

Automated hematology analyzers do not directly measure hematocrit, but rather calculate hematocrit from measurements of individual cell sizes and counts. The sample is diluted with an isotonic buffered aqueous solution and passed through a measuring orifice. Individual cells are counted and sized by one of two basic mechanisms. Either fluctuation in electrical conductivity or the scatter of collimated light, is measured as cells pass through the orifice. The hematocrit of the original sample is calculated from the number of cells, the sizes of the cells and the volume of diluted solution passing through the orifice.

Co-oximetry Methods

Like hematology analyzers, co-oximeters do not directly measure hematocrit. Hematocrit values are calculated from hemoglobin values that are measured by spectrophotometry. A fixed relationship between hemoglobin and hematocrit is used to calculate hematocrit.

METHOD COMPARISONS

The discrepancy between the hematocrit values determined by two different systems on an individual sample has three components: a random component, a systematic component and a method-dependent / sample-specific component.

Random Component

The random component results from the combination of each system's imprecision. The size of the component is different on each determination. The imprecision of the i-STAT System is typically about 0.6 %PCV to 0.7 %PCV (1 standard deviation).

Systematic Component

The systematic component results from differences in the systems' calibration, and is constant from sample to sample.

Method-Dependent / Sample-Specific Component

The method-dependent / sample-specific component results from the specific interferences which affect different measurement methods. Each sample has specific characteristics, which may cause different methods to have different types and sizes of measurement error.

The method-dependent / sample-specific component is commonly observed as a random difference between dissimilar methods. It can, however, also cause an apparent systematic difference component when a particular sample population has a systematic characteristic. For example, a population of samples with low mean cell hemoglobin concentration (MCHC) will cause a systematic negative bias on determinations by some automated hematology analyzers when compared to determinations from both microhematocrit and conductivity systems.

LIMITATIONS OF THE METHODS

Microhematocrit

Sources of error in the microhematocrit method are discussed in the Procedure for Determining Packed Cell Volume by the Microhematocrit Method,[1] and include sampling, tube, reading and packing errors.

Conductivity Methods

Electrolyte Concentration

The conductivity of the whole blood sample is dependent upon the concentration of electrolytes in the plasma portion. The i-STAT System corrects for the concentration of electrolytes using the measured value of sodium and potassium. The interference is minimized to an insignificant level.

Other Non-Conducting Elements[33-38]

The conductivity method does not distinguish red blood cells from other non-conducting elements such as proteins, lipids and white blood cells, which occupy volume in the sample. The i-STAT System is calibrated to read hematocrit accurately when these other elements are at normal levels.

Total Protein

At hematocrit levels less than 40 %PCV, the reading will increase by approximately 1 %PCV for each g/dL (10 g/L) the protein level is increased outside the normal range of 6.5 g/dL to 8.0 g/dL (65 g/L to 80 g/L). At hematocrit levels less than 40 %PCV, the reading will decrease by approximately 1 %PCV for each g/dL (10 g/L) the protein level is decreased outside the normal range of 6.5 g/dL to 8.0 g/dL (65 g/L to 80 g/L). At hematocrit levels greater than 40 %PCV the interference is about three quarters that size.[39]

It is important to be aware of the total protein level when using conductivity systems to monitor a patient on a cardiopulmonary bypass pump.[38] If albumin, or other colloid, is not added to the pump's priming solution, the plasma protein will drop by about 3 g/dL to 4 g/dL (30 g/L to 40 g/L). The conductivity reading will then be systematically low by 3 %PCV to 4 %PCV. For further information on the use of the coronary bypass mode on the i-STAT System see the Theory section of the i-STAT or i-STAT 1 System Manual.

It is also important to be aware that the total protein level in premature neonates can be in the range of 3.6 g/dL to 6.0 g/dL (36 g/L to 60 g/L).[40] Total protein levels may be low in burn patients and in patients receiving large volumes of saline-based fluids.

Lipids

Interference from lipids will be about two-thirds the size of the interference from proteins. The protein interference is larger because it is a charged non-conducting element.

White Blood Cells

Interference from white blood cells depends upon the size of the cell. As an example, the hematocrit reading will be increased by 1 %PCV when the white cell count is 50,000 per microliter, assuming the average white blood cell occupies twice the volume of an average red blood cell.

Automated Hematology Methods

Osmolality:[16-27]

Abnormal sample osmolality can create discrepant readings as the red cells shrink or swell to achieve osmotic balance with the isotonic (normal osmolality) diluent. Differences up to 10 %PCV have been reported for glucose concentrations in the range of 1000 mg/dL to 2000 mg/dL. Differences up to 5 %PCV have been reported for samples with low or high sodium concentrations.

Cold Agglutinins:[28-32]

Under the right conditions of diluent temperature, red blood cells from certain samples will clump together. The large clumps will not be recognized as red blood cells by certain automated hematology analyzers, and thus the overall red blood cell count and the calculated hematocrit, will be falsely low. In extreme cases, the hematocrit can read low by up to about 8 %PCV.

Mean Cell Hemoglobin Concentration:[11-15]

Red blood cells can deform under the pressure experienced when being sent through the measuring orifice. This is particularly true for electrical impedance methods. Cells with lower hemoglobin concentrations will deform to a greater degree. This can create errors as large as 3 %PCV.

Early authors attributed the discrepancy between automated hematology determinations and reference microhematocrit determinations to variabilities in trapped plasma on the microhematocrit determination.[5-9,10a,10b] Recent authors have recognized the substance of the discrepancy to be an interference on the automated method.

Co-oximetry Methods

The accuracy and precision of measured total hemoglobin from co-oximeters depends on the instrument's efficiency in hemolyzing the blood and the number of wavelengths used to determine hemoglobin. The calculation of hematocrit from measured hemoglobin assumes a normal MCHC. Deviation from a normal adult MCHC, e.g. in children, may give an inaccurate calculated hematocrit.[41] Other limitations of measuring total hemoglobin by spectrophotometric methods include the effect of sulfhemoglobin and fetal hemoglobin and hyperlipidemic plasma that may falsely elevate the hemoglobin.[42,43] An extremely high number of WBCs may also elevate the hemoglobin value resulting in an inaccurately calculated hematocrit.[44]

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Art: 714261-00E

i-STAT® TECHNICAL BULLETIN

K_2EDTA and K_3EDTA Customization for Hematocrit on the i-STAT® System

PURPOSE

This Technical Bulletin contains the information needed to select the K_2EDTA or K_3EDTA customization option for reporting hematocrit results on the i-STAT System.

HEMATOCRIT CALIBRATION

The reference method for hematocrit is the microhematocrit (MH) method. All instruments measuring hematocrit are expected to be traceable, or calibrated, to this reference method.[1-3]

The microhematocrit reference method described in CLSI H7-A3[3] permits both K_2EDTA and K_3EDTA anticoagulant sample collection tubes. K_3EDTA anticoagulant shrinks red blood cells relative to K_2EDTA anticoagulant, causing microhematocrit results from K_3EDTA samples (MH-K_3EDTA) to be lower by approximately 2 – 4% than results from K_2EDTA samples (MH-K_2EDTA).[3,4]

Consequently, instruments calibrated to MH-K_3EDTA report lower hematocrit results than analyzers calibrated to MH-K_2EDTA.

SELECTION OF THE K_2EDTA OR K_3EDTA CUSTOMIZATION SETTINGS ON THE i-STAT SYSTEM

i-STAT provides two customization settings for reporting hematocrit results: The "K_3EDTA" customization reports hematocrit results traceable to MH-K_3EDTA. The "K_2EDTA" customization reports hematocrit results traceable to MH-K_2EDTA.

For best agreement of i-STAT and hematology analyzer hematocrit results, the i-STAT customization setting is selected according to the calibration of the comparative hematology analyzer (MH-K_2EDTA or MH-K_3EDTA). (Note: The default setting on the i-STAT System is K_3EDTA.)

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If the calibration of a comparative method is uncertain, determine the customization setting by minimizing the average bias between methods as follows:

- Check that the results from hematocrit controls for both i-STAT and comparative methods are acceptable.

- If i-STAT hematocrit results obtained using the "K_3EDTA" setting are consistently lower than those on the comparative method, the "K_2EDTA" setting may be a better choice. If agreement is better after multiplying the "K_3EDTA"-customized i-STAT results by 1.0425, the customization setting should be switched to "K_2EDTA".

- Conversely, if i-STAT hematocrit results obtained using the "K_2EDTA" setting are consistently higher than those on the comparative analyzer, the "K_3EDTA" setting may be a better choice. If agreement is better after dividing the "K_2EDTA"-customized i-STAT results by 1.0425, the customization setting should be switched to "K_3EDTA".

- If an unacceptable system bias still exists, contact i-STAT Technical Support at 1-800-366-8020, option 1.

HEMATOLOGY ANALYZERS AND K_2EDTA AND K_3EDTA SAMPLE COLLECTION TUBES

Hematocrit results on hematology analyzers from samples collected in K_3EDTA and K_2EDTA tubes will be equivalent. This is because the osmotically-balanced diluent reverses the red blood cell shrinkage caused by the anticoagulant.[5] It should be clear that results from K_2EDTA and K_3EDTA tubes will be equivalent, but lower, on an analyzer calibrated to MH-K_3EDTA than on an analyzer calibrated to MH-K_2EDTA.

i-STAT has become aware that some customers have selected their i-STAT hematocrit customization according to the type of EDTA anticoagulant in the collection tube used for samples for the hematology analyzer. As explained above, the selection of the "K_2EDTA" or the "K_3EDTA" customization for i-STAT analyzers is based upon the microhematocrit method (MH-K_2EDTA or MH-K_3EDTA) to which the hematology analyzer is calibrated, rather than on the collection tube used for the hematology analyzer.

EXPECTED LEVEL OF METHOD AGREEMENT

Average i-STAT hematocrit results over a group of samples should normally agree with those from the comparative method within ± 2 %PCV at 29 %PCV and below, ± 3 %PCV from 30 to 50 %PCV, and within 10% above 50 %PCV when the following conditions are met:

- i-STAT analyzers are customized correctly.

- Comparative analyzer is calibrated correctly.

- Sample handling is optimal for both i-STAT and comparative methods.

- Samples are unaffected by factors listed in the i-STAT Cartridge and Test Information sheet for Hematocrit or in the user documentation for the comparative method.

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Art: 716240-00E

i-STAT® TECHNICAL BULLETIN

Calibration Verification and the i-STAT System

INTRODUCTION

Calibration Verification is a procedure performed to confirm that the calibration of an instrument or test system has remained stable throughout the reportable range. In many countries, this procedure is called a linearity check. Because of the inherent stability of the i-STAT System, Abbott Point of Care Inc. does not make any specific recommendations for the calibration verification procedure. Therefore, it is the responsibility of the laboratory to determine when and how this procedure should be performed. The information presented below is intended to help the laboratory make this determination.

In the United States, laboratory regulations (CLIA) require that for tests categorized as Non-Waived, a calibration verification procedure be performed and documented at least once every six months. The information presented below supports Abbott Point of Care Inc's. position that it is the cartridges, or more specifically, the sensors, rather than the analyzers that should be subject to the six-month check on the accuracy of the reportable range, and supports Abbott Point of Care Inc's. claim that all analyzers that pass the Electronic Simulator test are equivalent, which should preclude the testing of three levels, twice a year, on each and every analyzer on site.

In addition to the six-month time frame for a calibration verification procedure for Non-Waived tests, CLIA and laboratory accrediting bodies in the US list the following as possible reasons to perform calibration verification:

- validate the reportable range of a test before the test system is put into use.

- verify that a change in reagent lot numbers does not affect either the reportable range or control values.

- troubleshoot when control values are out-of-range.

- verify that results have not been affected by maintenance or repair procedures.

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STABILITY OF CALIBRATION IN THE i-STAT SYSTEM

The i-STAT System is a unit-use testing system. Components that cause shifts and drifts in results in multi-use analyzers: sensors (electrodes), calibration solution, fluid-handling channels and pumps, are housed in a disposable test cartridge. The sensors are exposed to sample only once, so there is no protein build-up which is a major cause for deterioration of sensor slope and the need to calibrate and/or verify calibration on a frequent basis in multi-use analyzers.

The stability and consistency of the manufacturing process allow the slope of the sensors to be programmed into the analyzer's software. A one-point calibration to set the intercept accounts for any day-to-day variation in testing conditions. When stored according to directions, the cartridges are stable up to the expiration date.

The analyzer houses the mechanical and electrical systems necessary to control fluid movement within the cartridge, control the temperature when measurements are performed at 37°C, measure barometric pressure, measure electrical signals generated by the sensors and display and transmit results. The analyzer's functions are factory calibrated to specifications that are programmed into the analyzer along with acceptability limits, which when exceeded cause the analyzer to display quality check messages or to display *** rather than results.

The accuracy of results and dependability of the internal quality check system depend upon the ability of the analyzer to take accurate and sensitive signal readings from the sensors. To check this function, i-STAT developed an electronic control device. The Electronic Simulator simulates two levels of electronic signals that stress the analyzer's signal detection function both below and above the reportable ranges. Injecting signals directly into the analyzer allows very tight control limits to be set. Control limits for liquid controls are set wide enough to allow for sensor-to-sensor variation. All analyzers that pass the Electronic Simulator test are equivalent and any variations in results are caused by within and between lot variations in the cartridges.

The combination of unit-use cartridges, inherently stable electronics of the analyzer, and reliability of the Electronic Simulator check provides the stability needed for a point-of-care testing system and reduces the need for frequent stability or calibration verification checks.

VALIDATING THE REPORTABLE RANGE

The accuracy of results over the entire reportable range could be assessed by testing the same patient samples on the new system and on a system with known accuracy and comparing results using an acceptable difference criteria. However, it is difficult to find samples that cover the low and high ends of the reportable ranges of many analytes. Ideally, the samples used to validate the ranges should have the same matrix as the patient samples. Tonometered blood can be used to validate the ranges for $P\text{CO}_2$ and $P\text{O}_2$. But for most analytes, there are no whole blood samples commercially available for this purpose.

Although the i-STAT Calibration Verification Set is aqueous-based, the target values have been determined over many lots of cartridges and results on these solutions when compared to the target values should indicate the performance of a particular lot of cartridges.

ASSESSING LOT-TO-LOT VARIATION

Lot-to-lot variation over the entire reportable range for any reagent system could be assessed by testing calibration verification solutions on old and new lots in parallel. This procedure should be suspended once it has been determined that lot-to-lot variation is acceptable. Quality controls samples with concentrations at decision points should always be used to assess new lots or reagent before results are reported.

Because the manufacturing process for the cartridges produces consistent lots with little lot-to-lot variation, Abbott Point of Care Inc. does not make any recommendations for this procedure. Each new lot of cartridges should be assessed using the i-STAT quality control solutions according to the procedure in the System Manual.

TROUBLESHOOTING

Should quality control sample results fall outside of the acceptable ranges, calibration verification samples with very low or very high concentrations could be helpful in characterizing a reagent problem.

The i-STAT System was designed so that the intended users, who are not familiar with laboratory procedures, cannot make any adjustments that would affect results. The characteristics of the sensors are well known and results of control solutions would be sufficient for Technical Support specialists to help users resolve control out-of-range problems.

VERIFYING THAT RESULTS HAVE NOT BEEN AFFECTED BY MAINTENANCE OR REPAIR PROCEDURES

In multi-use systems, reagents and samples are run through the analyzer and, therefore, there should be a method of checking that all components are performing together according to specifications after any one component is affected. Calibration verification solutions can be used to verify that the calibration or slope of the measuring system has not been affected by the maintenance or repair procedure.

The user cannot perform any maintenance procedures on the i-STAT System. However, the software in the analyzer is updated periodically – a procedure that potentially could cause a change in results. In fact, software updates are released to ensure that results do not change over time. Calibration verification solutions could be tested to verify that results have not been affected. This procedure should be suspended or replaced with controls once it has been determined that software updates do not affect results. Since i-STAT has been effectively updating software for over 10 years, this procedure is not part of Abbott Point of Care Inc's. recommended quality program.

Repaired and newly purchased analyzers are received with factory calibration. Again, the Electronic Simulator can better assure that the analyzer's most important function is within factory specifications than calibration verification or control solutions.

Testing calibration verification samples or comparing patient sample results on a new or repaired analyzer with an older analyzer will assess cartridge performance only. Any variations in analyzer performance will not be statistically discernable above the performance of the cartridges. When multiple analyzers are to be used at a facility, Abbott Point of Care Inc. recommends including at least two analyzers in any performance verification studies so that statistics reflect the "system."

i-STAT CALIBRATION VERIFICATION PRODUCTS

Product Title	Applicable Cartridges	Analytes	Available Levels
i-STAT Calibration Verification Set	G, Crea, E3+, EC4+, 6+, EC8+, G3+, EG6+, EG7+, CG4+, CG8+ and CHEM8+	Sodium Potassium Chloride Ionized Calcium pH $P\mathrm{CO}_2$ $P\mathrm{O}_2$ TCO_2 Glucose Lactate BUN/Urea Creatinine	1, 2, 3, 4, and 5
i-STAT TriControls Calibration Verification Set	G, Crea, E3+, EC4+, 6+, EC8+, G3+, EG6+, EG7+, CG4+, CG8+ and CHEM8+	Sodium Potassium Chloride Ionized Calcium pH $P\mathrm{CO}_2$ $P\mathrm{O}_2$ TCO_2 Glucose Lactate BUN/Urea Creatinine Hematocrit	1, 2, 3, 4, and 5
i-STAT CHEM8+ Calibration Verification Level 1B	CHEM8+	TCO_2	i-STAT CHEM8+ Level 1B material is available for purchase for customers who want to test lower levels of TCO_2.
i-STAT cTnI Calibration Verification Control Set	cTnI	cTnI	1, 2, and 3
i-STAT BNP Calibration Verification Control Set	BNP	BNP	1, 2, and 3
i-STAT CK-MB Calibration Verification Control Set	CK-MB	CK-MB	1, 2, and 3
i-STAT β-hCG Calibration Verification Kit	β-hCG	β-hCG	1, 2, and 3

When performing the calibration verification procedure to meet a six-month calibration verification requirement, include each sensor and a representative selection of analyzers.

NOTES:

Calibration Verification or a linearity check for hematocrit can also be performed by a manual method using blood collected in lithium heparin tubes and manipulated to create three levels of hematocrit. Target values for Hematocrit for this manual method can be obtained from the bench top lab analyzer.

The upper limit of the reportable range for PO_2 is 800 mmHg. The highest PO_2 level in the i-STAT Calibration Verification set is just over 450 mmHg. Oxygen levels above 450 mmHg are so unstable in aqueous solutions that it would be impossible to make reliable measurements above 450 mmHg. Whole blood samples can be tonometered with 100% oxygen to create a sample around 700 mmHg at sea level.

REFERENCE

Code of Federal Regulations, 42CFR493, Subpart K – Quality System For Non-Waived Testing, §493.1255 – Standard: Calibration And Calibration Verification Procedures. (January 24, 2003)

i-STAT® TECHNICAL BULLETIN

ACT Test Result Calibration Options: PREWARMED vs. NON-PREWARMED Result Calibration Modes for the i-STAT®1 Analyzer

BACKGROUND

The Activated Clotting Time (ACT) test has been in existence for over 30 years. It is the most popular test for measuring the effect of heparin administered during an interventional procedure. By placing an activator in the test chamber, the blood sample is "activated" to promote clotting. When heparin is present in the sample, the clotting is delayed in proportion to the amount of "anticlotting" effect of the heparin.

Since its inception, numerous changes have taken place to ACT tests, including increased automation and decreased sample volume. Today, there are many new, fully automated, low blood volume ACT tests on the market, in addition to the older, macro blood volume, semi-automated tube-based systems (*i.e.*, Hemochron®, Actalyke™). The micro sample ACT systems typically employ test cartridges or cards (instead of tubes), and all have incorporated an automatic test cycle prewarming step that brings the ACT testing chamber to 37°C prior to initiating the clotting reaction. As blood clotting is an enzymatic process, the temperature at which the clotting cycle takes place has a marked impact on the rate at which the blood clot forms. The ACT tests that incorporate a prewarming step allow the entire clotting reaction to take place at 37°C. ACT tests that do not use a prewarming step are subject to a delay before the blood specimen reaches (and stabilizes at) 37° degrees; the actual time needed to reach 37°C is dependant on the starting temperature of the sample test tube. For example, a 30°C blood sample placed into a (non-prewarmed) 25°C ACT tube will take a few minutes before the test environment (blood, reagent, tube) stabilizes at 37°C. The result of this thermal delay is an increase in the reported ACT clot time that will depend on sample tube temperature.

ACT Instruments **WITH** an automatic prewarming step	ACT Instruments **WITHOUT** an automatic prewarming step
Medtronic® ACTII (plus)	Hemochron 801/401/8000/Response
Medtronic HMS (plus)	Actalyke
Bayer/TAS HMT	
Roche ACT	
Hemochron® Jr. (Signature/PCL)	
i-STAT	

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i-STAT ACT CALIBRATION

Currently, the i-STAT® Celite® ACT and i-STAT® Kaolin ACT tests are factory calibrated by mathematically adjusting the raw i-STAT "clot time" to match the Hemochron® Celite tube result. This calibration is performed by testing cartridges and Hemochron Celite tubes side by side, using a range of heparinized, non-hemodiluted whole blood samples, and using **Hemochron tubes prewarmed to 37ºC.**

Customers who are familiar with macro-sample ACT methods like Hemochron and Actalyke™, and who do not preheat their tubes prior to each test, have found that the bias in results between their previous ACT method and the i-STAT ACT may require changing familiar clotting time target values. In order to ease the changeover to the i-STAT ACT method under these circumstances, i-STAT now provides a choice between the current 37ºC result calibration and a new "non-prewarm" (or ambient temperature) result calibration. The additional calibration mode allows an i-STAT ACT cartridge to deliver results that will be a closer match for those users who are familiar with macro-sample methods without automatic prewarming cycles, and should reduce the need to make large changes to ACT target times or ranges. Since micro-sample methods (Medtronic HR-ACT, Hemochron Jr. ACT+) already incorporate preheating of the test cuvettes, users with ACT target times and ranges based on these methods should continue to use their current i-STAT 37ºC calibration.

REPRESENTATIVE DATA

Effect of Sample Tube Temperature on Hemochron ACT Results using Paired Samples: Prewarmed sample tubes vs. Non-prewarmed sample tubes.

Hemochron ACT: Effect of prewarming tubes on the ACT time

Bias in Hemochron ACT results when tubes are non-prewarmed
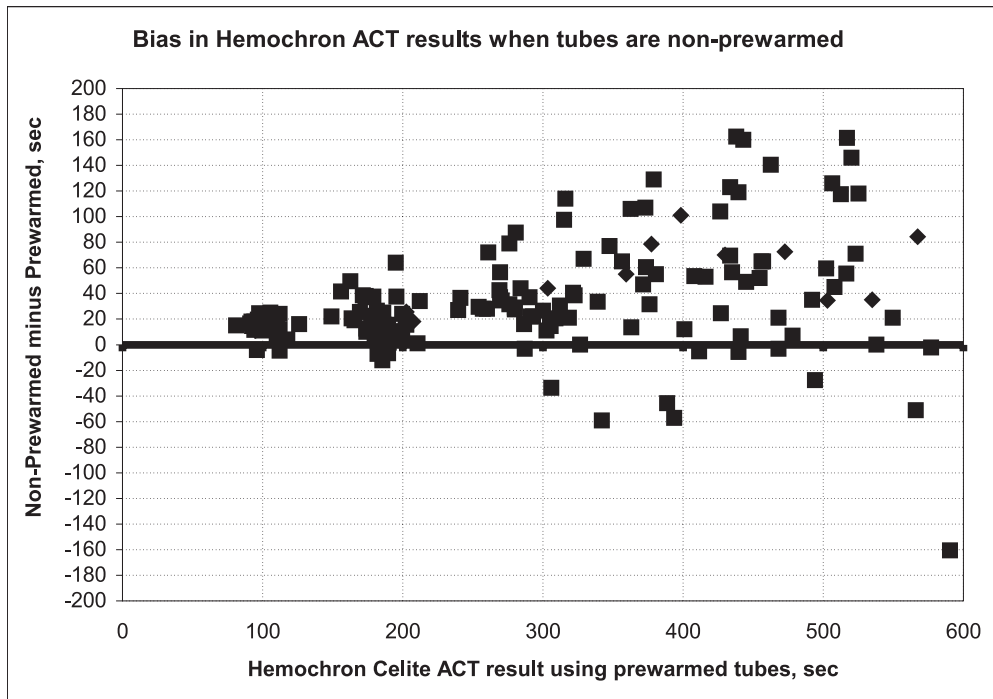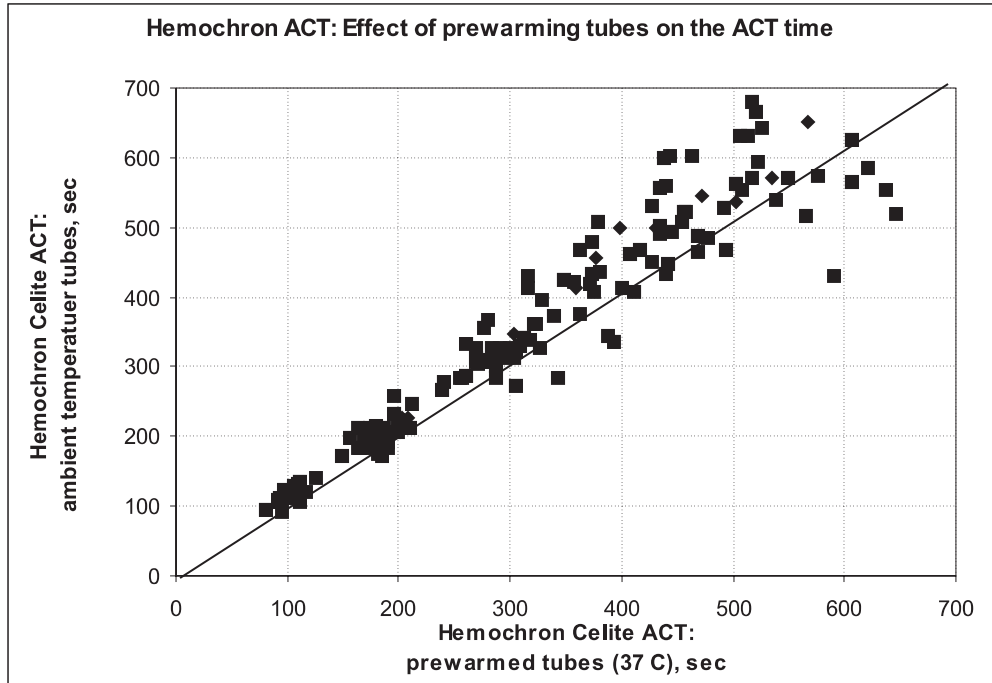
i-STAT Celite ACT vs. Room Temperature Hemochron FTCA510: Prewarmed **(PREWRM)** vs. Non-prewarmed **(NONWRM)** calibration modes.

**i-STAT Celite ACT PREWRM Calibration
vs. Hemochron FTCA510
CATH LAB SAMPLES**

**i-STAT Celite ACT NONWRM Calibration
vs. Hemochron FTCA510
CATH LAB SAMPLES**

Art: 715617-00D
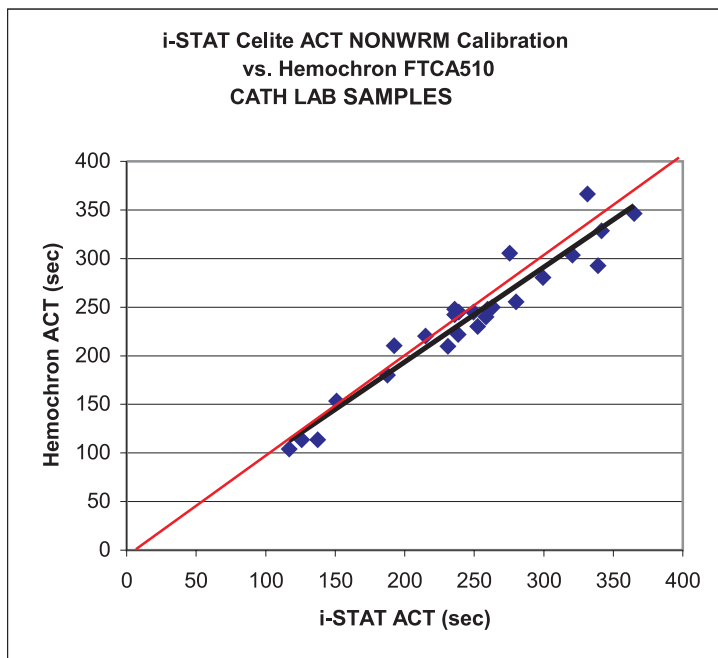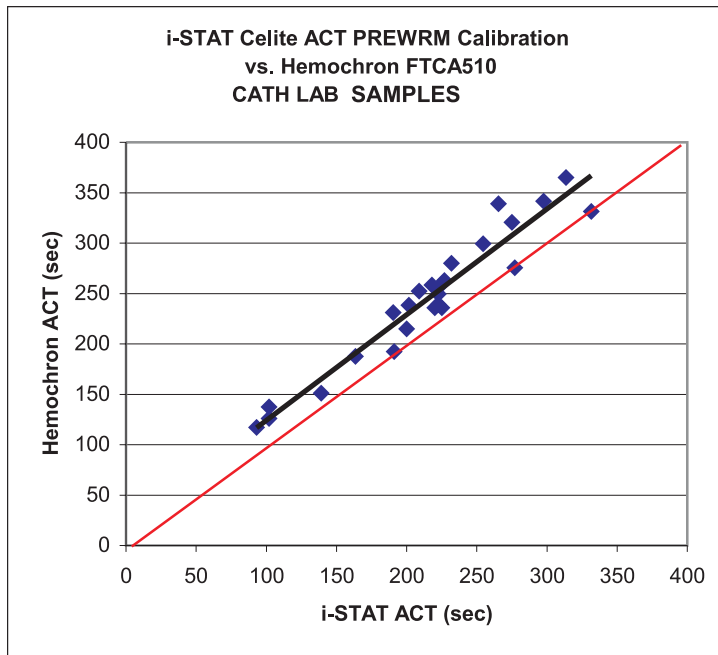
ANALYZER DISPLAY AND CDS CHANGES

Due to the new ACT result calibration option, there are several changes to the analyzer display as well as to the Central Data Station (CDS). Major changes are noted below:

- The i-STAT PCA and BAM are NOT capable of offering the new ACT result calibration option. All PCA and BAM ACT results continue to use the original ACT calibration (PREWRM). To clearly identify this calibration, ACT results reported on the i-STAT PCA will show PREWRM on the result screen.

```
┌─────────────────┐   ┌─────────────────┐
│     ACT-C       │   │     ACT-K       │
│    PREWRM       │   │    PREWRM       │
│                 │   │                 │
│  ACTsec    224  │   │  ACTsec    216  │
│                 │   │                 │
│                 │   │                 │
│                 │   │                 │
│ ┌─────────────┐ │   │ ┌─────────────┐ │
│ │#42212       │ │   │ │#42212       │ │
│ │10:10  09JUL03│ │   │ │10:10  09JUL03│ │
│ └─────────────┘ │   │ └─────────────┘ │
│ ▐PAGE▌ ▐MENU▌   │   │ ▐PAGE▌ ▐MENU▌   │
└─────────────────┘   └─────────────────┘
```
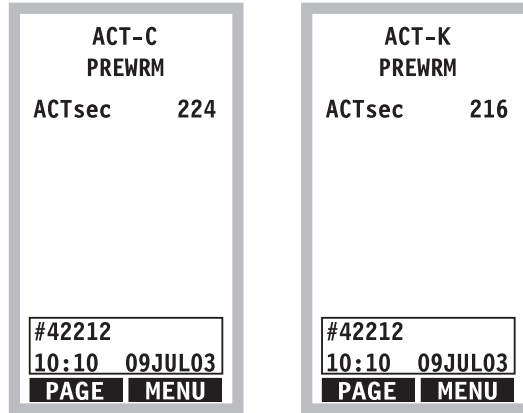
- The ACT test results that will be displayed on the i-STAT 1 analyzer now show the calibration setting that was used to perform the ACT calculations.

```
┌──────────────┐ ┌──────────────┐ ┌──────────────┐ ┌──────────────┐
│ Pt: 100025   │ │ Pt: 100025   │ │ Pt: 100025   │ │ Pt: 100025   │
│ 15:49 30JUL03│ │ 15:56 30JUL03│ │ 15:49 30JUL03│ │ 15:56 30JUL03│
│ i-STAT ACT -C│ │ i-STAT ACT -C│ │ i-STAT ACT -K│ │ i-STAT ACT -K│
│   PREWRM     │ │   NONWRM     │ │   PREWRM     │ │   NONWRM     │
│ ACTsec   224 │ │ ACTsec   249 │ │ ACTsec   224 │ │ ACTsec   249 │
│              │ │              │ │              │ │              │
│              │ │              │ │              │ │              │
│   ➡ Page     │ │   ➡ Page     │ │   ➡ Page     │ │   ➡ Page     │
│ 1-Test Options│ │ 1-Test Options│ │ 1-Test Options│ │ 1-Test Options│
└──────────────┘ └──────────────┘ └──────────────┘ └──────────────┘
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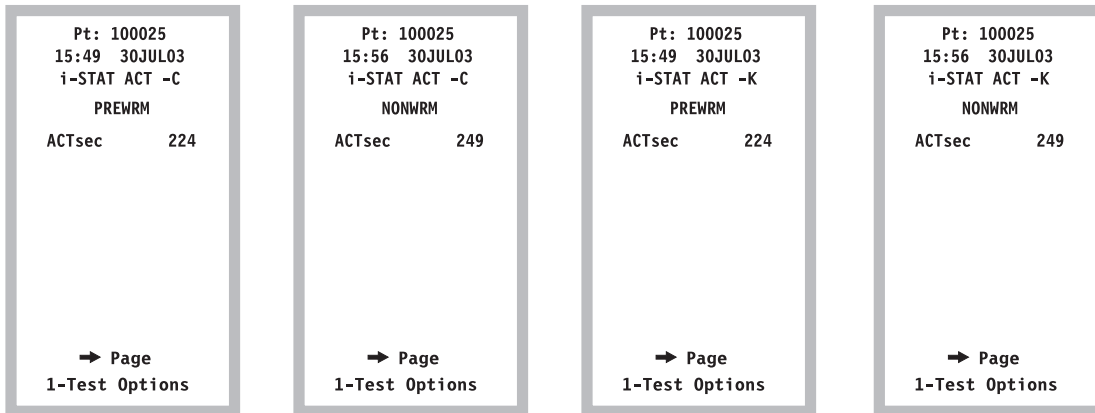
- The i-STAT 1 analyzer is capable of offering both the **NONWRM** and **PREWRM** ACT customization settings. These customizations can be viewed, selected and changed via the RESULTS CUSTOMIZATION section on the i-STAT 1 analyzer
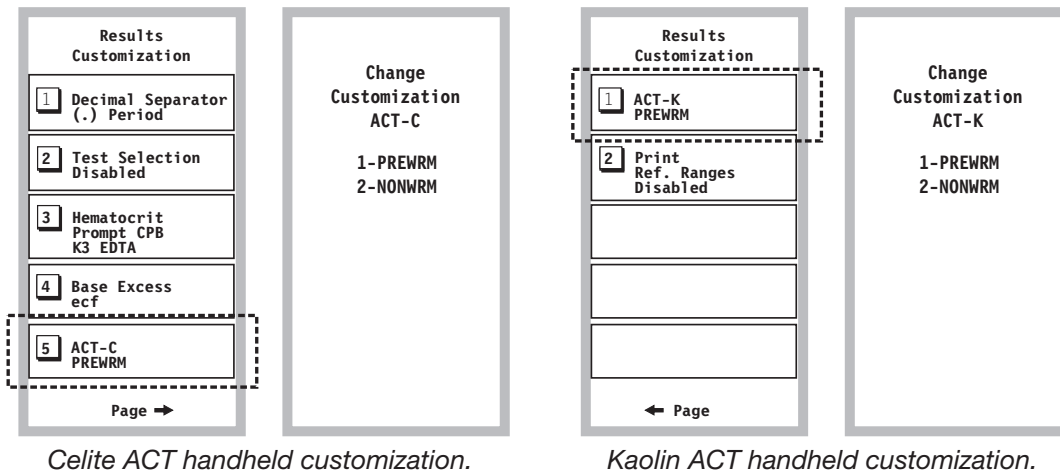
Celite ACT handheld customization.   Kaolin ACT handheld customization.

- For i-STAT 1 analyzers used in conjunction with CDS version 5, the new ACT customization options are located on the RESULTS tab of the Preferences section of the individual customization profile (see highlight). Users should select the desired calibration mode for each i-STAT ACT type (Celite and/or kaolin).
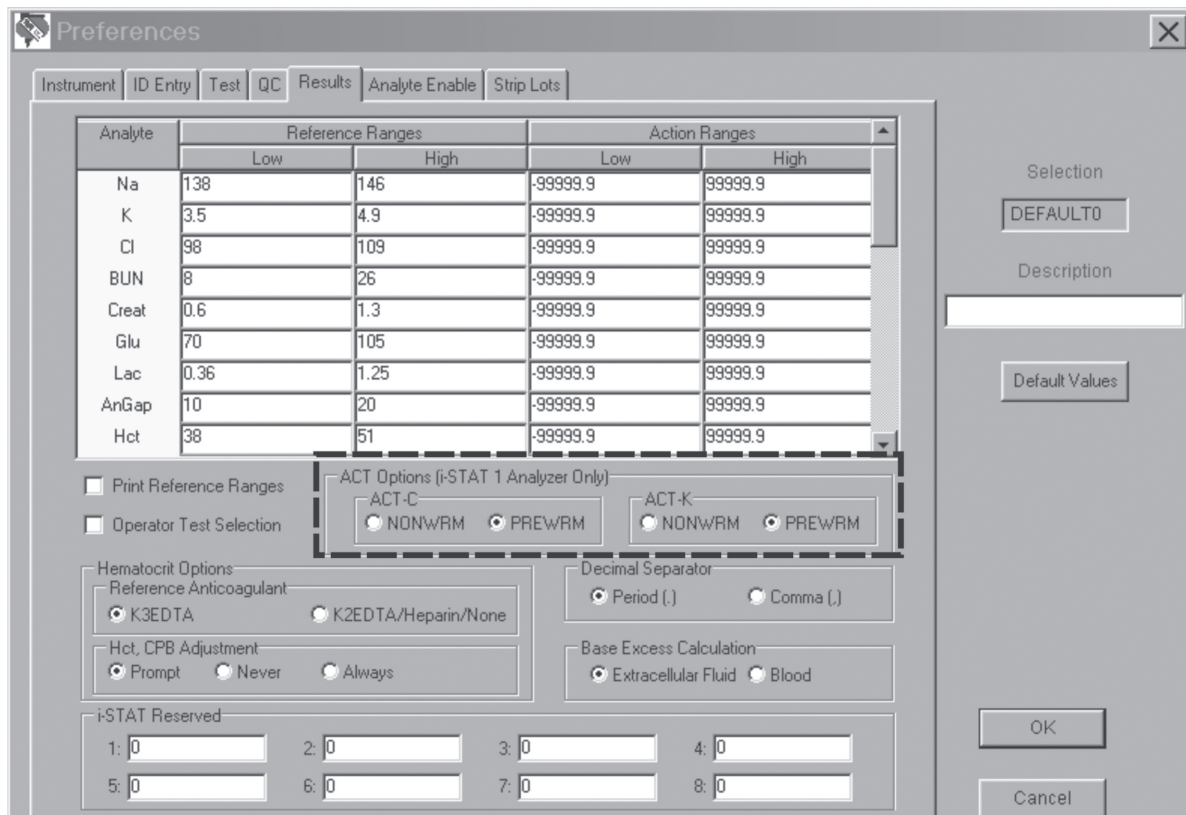
LIMITATIONS AND WARNINGS

- The NONWRM calibration mode applies to the Patient Path only, and will not be applied to the Control or Proficiency Testing pathway. *Control or Proficiency samples run in the Patient Pathway may produce erroneous results.*

- Different locations within a given hospital may utilize different calibration modes/customization profiles. Prior to testing patient samples, ensure the appropriate calibration mode is employed.

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Actalyke® is a registered trademark of Helena Laboratories

Hemochron® is a registered trademark of International Technidyne Corporation

Hemotec® is registered trademark of Medtronic Corporation

Celite is trademark of the Celite Corporation

Art: 715617-00D

i-STAT® TECHNICAL BULLETIN

i-STAT® Celite® ACT and i-STAT® Kaolin ACT Heparin Linearity Procedure

INTRODUCTION

The i-STAT Celite ACT and the i-STAT Kaolin ACT tests are intended for *in vitro* diagnostic use. This test can be performed at the bedside using venous or arterial whole blood. The i-STAT Celite ACT is commonly used for heparin anticoagulation monitoring for adults during cardiopulmonary bypass (CPB) surgery and percutaneous transluminal coronary angioplasty (PTCA). The i-STAT Kaolin ACT is used for heparin anticoagulation monitoring during cardiopulminary bypass (CPB) surgery, and can be used in the presence of aprotinin. The i-STAT ACT tests can be performed using the i-STAT Portable Clinical Analyzer or i-STAT 1 Analyzer. The reportable range of the i-STAT ACT test is from 50-1000 seconds.

The i-STAT ACT tests have demonstrated linearity between 0.0 and 6.0 units of heparin in blood samples from normal, healthy volunteers.

An *in vitro* heparin sensitivity curve was generated by adding increasing amounts of heparin to aliquots of normal donor blood (See graph below which serves as an example only. Each patient demonstrates a unique dose-response curve.)

Citrated Heparin Linearity

$y = 126.23x + 42.018$
$R^2 = 0.9619$

ACT (sec)

Units Hep (/ml)

Abbott
Point of Care
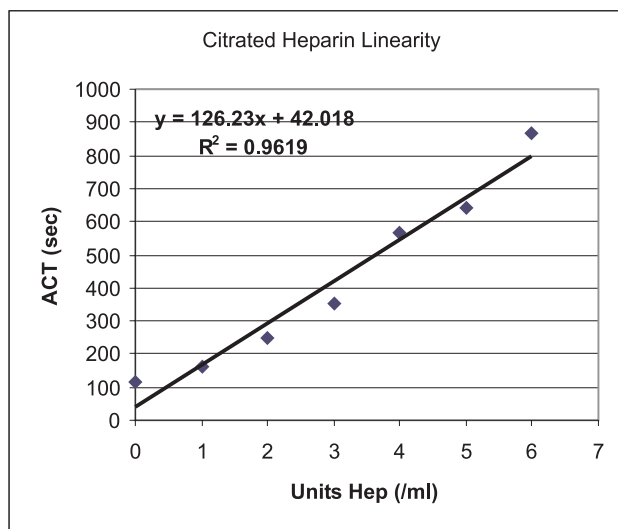
If an attempt is being made to reproduce and demonstrate the manufacturer's claims as they relate to the linearity and sensitivity of an ACT test, the following procedure may be used. An *in vitro* laboratory assay of heparin sensitivity is a universally accepted method of evaluating the ACT assay performance. An acceptable degree of linearity in a heparin dose-response sensitivity curve is an indication of ACT performance validation. Heparin sensitivity curves are generated using either citrated or fresh donor whole blood, where incremental concentrations of heparin are added to aliquots of the blood specimen. The i-STAT ACT tests can be performed using these specimens.

When performing the procedure on an i-STAT 1 Analyzer, run the samples in the Patient Mode, as there are too many levels to run them in the Calibration Verification Mode.

LINEARITY PROCEDURE FOR USING CITRATED WHOLE BLOOD

Materials
- i-STAT Celite ACT cartridges or i-STAT Kaolin ACT cartridge (14)
- Plastic test tubes, no additives (7)
- Large collection tube for heparin dilution, 10 mL minimum, no additives (1)
- Large plastic collection tube for blood pooling, 10 mL minimum, no additives (1)
- 1,000 units/mL USP Heparin (beef lung or porcine)
- Isotonic Saline (9.0 mL)
- 0.025M Calcium Chloride
- Precision pipettes (1,000 µL)
- 3.2 or 3.8% Sodium Citrate evacuated blood collection tubes (blue top) for 9mL collection (i.e., 2 x 4.5mL tubes).

Procedure
Note: *Although clinical testing utilizes fresh whole blood exclusively, for the purposes of the linearity assessment, citrated whole blood can be substituted.*

Note: *When using a citrated whole blood source clotting times may be slightly higher than when using fresh whole blood.*

1. Obtain 14 i-STAT ACT cartridges and two i-STAT Analyzers.

2. Using a standard pharmaceutical heparin preparation (either beef or porcine derived material from any manufacturer), dilute the heparin using saline to a concentration of 100 units/mL of total volume. This can be accomplished by adding 9.0 mL of saline to 1.0 mL of standard USP heparin supplied at 1,000 units/mL.

3. Label seven (7) plastic test tubes in the following manner: "A", "B", "C", "D", "E", "F", and "G". Dispense the following quantities of the diluted heparin into the respective test tubes. The final concentration of heparin in the plastic test tubes after the addition of blood and calcium can be found in the table below.

Tube	Amount of Heparin (µL)	Final Heparin Concentration (units/mL)	Total Heparin Units
A	0	0	0
B	10	1.0	1.0
C	20	2.0	2.0
D	30	3.0	3.0
E	40	4.0	4.0
F	50	5.0	5.0
G	60	6.0	6.0

4. Obtain at least two 4.5 cc blue top (3.8% or 3.2% sodium citrate) tubes. Gently mix the tubes end to end 10 times. (Note: a total of 9.0 mL of citrated whole blood is needed and pooled in the larger collection tube)

5. Accurately dispense 0.70 mL of the citrated blood sample to each one of the seven test tubes prepared in step 3. ("A", "B", "C", "D", "E", "F" and "G"). These are the tubes to which the heparin has previously been added. After adding the blood sample, gently mix the tubes by inversion.

6. Starting with test tube "A" add 0.30 mL of 0.025M Calcium Chloride to the tube. Mix thoroughly. (Do not add Calcium Chloride to the tube until ready to run the cartridge(s) for that heparin level.)

7. Immediately, use a plastic transfer pipet or a syringe to dispense the mixture into the sample well of 2 ACT cartridges. Begin the test.

8. Record the ACT results.

9. Repeat steps 6 through 9 for all tubes "B", "C", "D", "E", "F" and "G".

    Note: Before testing tubes B – G, mix gently by inversion.

10. Record the clotting times and graph the results using, "Avg. ACT seconds" on the y-axis and "Heparin Concentration" (units/mL) on the x-axis.

Result Interpretation

Inspection of the dose-response curve will identify a linear sensitivity response. Linearity is defined statistically by the correlation coefficient (r value) of the assay, which should be ≥ 0.88.

Notes:

Due to the variability of heparin sensitivity, high levels may yield out of range high results. An intermediate amount of heparin can be used to perform linearity (e.g. 35 μL). The actual values obtained for a given heparin level will vary among donors. The heparin type (beef or porcine), manufacturer source and lot number of the heparin preparation will also affect results. The maximum concentration of heparin at which a donor's blood will clot is dependent upon physiologic characteristics of the donor. Extremely elevated clotting times can be excluded from the analysis.

LINEARITY PROCEDURE FOR USING FRESH WHOLE BLOOD

Materials
- i-STAT Celite ACT or i-STAT Kaolin ACT cartridges (14)

- Plastic test tubes, no additives (7)

- Large plastic collection tube for heparin dilution, 20 mL, no additives (1)

- 1,000 units/mL USP Heparin (beef lung or porcine)

- Isotonic Saline (9.0 mL)

- Precision pipettes (1,000 uL)

Procedure
1. Obtain 14 i-STAT ACT cartridges and at least two i-STAT Analyzers.

2. Using a standard pharmaceutical heparin preparation (either beef or porcine derived material from any manufacturer), dilute the heparin using saline to a concentration of 100 units/mL of total volume. This can be accomplished by adding 9.0 mL of saline to 1.0 mL of standard USP heparin supplied at 1,000 units/mL.

3. Label seven (7) plastic test tubes in the following manner: "A", "B", "C", "D" "E", "F" and "G".

4. Dispense the following quantities of the diluted heparin into the respective test tubes. The final concentration of heparin in the plastic test tubes after the addition of 1.0 mL fresh whole blood can be found in the table below.

Tube	Amount of Heparin (µL)	Final Heparin Concentration (units/mL)	Total Heparin Units
A	0	0	0
B	10	1.0	1.0
C	20	2.0	2.0
D	30	3.0	3.0
E	40	4.0	4.0
F	50	5.0	5.0
G	60	6.0	6.0

5. Using a butterfly needle and a 10 cc syringe, obtain 9.0 cc of fresh whole blood from a normal healthy donor who is not currently taking medications.

6. Accurately dispense 1.0 mL of the fresh whole blood sample to each of the seven (previously prepared) plastic test tubes A to G and gently mix by inversion.

7. Immediately using plastic transfer pipet or a syringe withdraw about 0.3 mL of the unheparinized blood from tube A and dispense into 2 ACT cartridges. Begin the test.

8. Record the ACT results.

9. Repeat steps 7-9 for blood samples "B", "C", "D" "E", "F" and "G".

    Note: Before testing tubes B – G, mix gently by inversion.

10. Record the clotting times and graph the results, using "Avg. ACT seconds" on the y-axis and "Heparin Concentration" (units/mL) on the x-axis.

Result Interpretation

Inspection of the dose-response curve will identify a linear sensitivity response. Linearity is defined statistically by the correlation coefficient (r value) of the assay, which should be ≥ 0.88.

Note: Due to variability of heparin sensitivity, high levels may yield out of range high results. An intermediate amount of heparin can be used to perform linearity (e.g. 35 µL). The actual values obtained will vary among donors. The heparin type (beef or porcine), manufacturer source and lot number of the heparin preparation will also affect results. The maximum concentration of heparin at which donor blood will clot is dependent upon physiologic characteristics of the donor. Extremely elevated clotting times can be excluded from the analysis.

Heparin Linearity Data Collection Sheet

Operator Name	

Sample Type	Citrated Whole Blood ☐ Fresh Whole Blood ☐

Date	Facility Name	
	Analyzer Serial Number	
	i-STAT ACT Lot#	

Hep Conc (U/ml)	Clotting Time (sec)		
	ACT 1 (sec)	ACT 2 (sec)	Average (sec)
0			
1			
2			
3			
4			
5			
6			

i-STAT is a registered trademark of Abbott Laboratories, East Windsor, NJ.

Celite is a registered trademark of Celite Corporation, Santa Barbara,CA, for its diatomaceous earth products.

Art: 714547-00F

i-STAT® TECHNICAL BULLETIN

Support Services

Abbott Point of Care and its distributors are committed to helping you resolve any problems with the i-STAT® System: i-STAT 1 Handheld, cartridges, accessories and data management software. For technical assistance within the United States, please call Technical Services at 800-366-8020 toll free. Outside the U.S., please contact your local i-STAT distributor.

NORTH AMERICA

USA
Abbott Point of Care
400 College Road East
Princeton, NJ USA 08540
Tel: +800-366-8020, option 1
Tel: +800-284-0702 (waived customers)
Email: techsvc@apoc.abbott.com

CANADA
Abbott Point of Care
400 College Road East
Princeton, NJ USA 08540
Tel: +800-366-8020, option 1
Email: techsvc@apoc.abbott.com

AFRICA

ALGERIA
Vicralys S.A.R.L.
Chaabani Lot 9 Batiment 06
Val d'Hydra
Algiers, Algeria 16035
Tel.No.: 213770947856

BURKINA FASO
TM Diffusion Sarl
262 Avenue President Maurice
YAMEOGO, 06 BP 9186
Ouagadougou 06
Burkina Faso
Tel. No.: +226 70193555

ANGOLA
Magnamed
Rua Prof Francisco Gentil, n° 22F
2620-097 Póvoa de Santo Adrião
Portugal
Tel.No.: +351 21 938 32 40

EGYPT
United Group for Engineering Business
18th Elkhalefa Elmamoun St.
Heliopolise
Cairo, Egypt
Tel.No.: 201111117828

BURKINA FASO
Obsidian Health Ltd
Cosmo Business Park
Malibongwe Drive
Randburg, South Africa 2188
Tel.No.: +27 87 3535600

GHANA
Phillips Pharmaceuticals (Ghana) Ltd.
141 Tsuibleoo, Near Light House Church
North Kaneshie
Accra, Ghana
Tel.No.: +233 2670 891 94

Abbott Point of Care

KENYA
Phillips Healthcare Technologies Ltd
Phillips Business Park
Mombasa Road
Nairobi, Kenya
Tel.No.: 254-7336-12025

LESOTHO
Obsidian Health Ltd
Cosmo Business Park
Malibongwe Drive
Randburg, South Africa 2188
Tel.No.: +27 87 3535600

LIBYA
AI- Harameen Pharmaceutical
Medical Supplies
Extension of Al Saraj
Street After Audi Showroom
Tripoli, Libya
Tel.No.: 201 00 3333 444

MADAGASCAR
Techno Scientific Ltd.
Hill Lane
Solferino, Phoenix
Mauritius
Tel.No.: +230 424 1881

MAURITIUS
Techno Scientific Ltd.
Hill Lane
Solferino, Phoenix
Mauritius
Tel.No.: +230 424 1881

MOROCCO
Masterlab Sarl
22 Rue IBN Tayeb Kadiri Les
Orangers Rabat
Rabat, Morocco
Tel. No.: 212661208038

MOZAMBIQUE
Magnamed
Rua Prof Francisco Gentil, n° 22F
2620-097 Póvoa de Santo Adrião
Portugal
Tel.No.: +351 21 938 32 40

MOZAMBIQUE
Afri Farmacia LDA
Viswamitra JTL
Av Das FPLM 1277
Maputo 1100, Mozambique
Tel. No.: 0025821462248

NIGERIA
Phillips Pharmaceuticals (Nigeria) Ltd
122-132 Afprint Industrial Estate
Apapa Oshodi Expressway
Iyana-Isolo, Lagos, Nigeria
Tel.No.: 2348056292422

NIGERIA
QDT Solution
258 Borno Way
Ebute Meta
Yaba
Lagos, Nigeria
Tel. No.: +44 7808 589 217

REUNION
Techno Scientific Ltd.
Hill Lane
Solferino, Phoenix
Mauritius
Tel.No.: +230 424 1881

SOUTH AFRICA
Obsidian Health Ltd
Cosmo Business Park
Malibongwe Drive
Randburg, South Africa 2188
Tel.No.: +27 87 3535600

TANZANIA
Phillips Pharmaceuticals (Tanzania) Ltd
Vingunguti Industrial Area
P.O. Box 737
Dar Es Salam, Tanzania
Tel. No.: 255782637336

TUNISIA
Madis Medical
Immeuble Le Capitole, Appt B1
Avenue Hedi Nouri
Ennasr 2 2037 Tunisia
Tel. No.: +96171786444;
          +21623477777

UGANDA
Phillips Pharmaceuticals (Uganda)
Ltd
N-5 Madhavani Complex
5th Street, Industrial Area Bugolobi
Kampala, Uganda
Tel.No.: 256 772 518 681

ZAMBIA
Obsidian Health Ltd
Cosmo Business Park
Malibongwe Drive
Randburg, South Africa 2188
Tel.No.: +27 87 3535600

ZIMBABWE
Healthyard Laboratories Pvt Ltd
Cooksey House, 2 Simon Mazorodze Rd
Southerton, Harare, Zimbabwe
AZ1095
Tel. No.: +263778401114

ASIA/PACIFIC (EXCLUDING CHINA)

AUSTRALIA
Abbott Australia
299 Lane Cove Road
Macquarie Park
NSW 2114
Australia
Tel: +61 2 9857 1111

BRUNEI
Transmedic Pte Ltd.
5, Jalan Kilang Barat
9th Floor Petro Centre
Singapore 159349
Tel: +65 6 7371 945

HONG KONG
Bio-Asia Diagnostics Company Ltd.
Unit 1-3, 20F
CRE Centre, 889 Cheung
Sha Wan Road, Cheung Sha Wan
Kowloon
Hong Kong
Tel: +852 27870906

HONG KONG
Kingsford Far East Ltd
Unit 06B, 38 F Cable TV Tower
9 Hoi Shing Rd, Tsuen Wan
Hong Kong
Tel: 852 23480433

INDIA
Sandor Medicaids Private Ltd.
8-2-326/5, Road No. 3
Banjara Hills
Hyderabad, India 500 034
Tel: +91 40 233 570 48

INDIA
Majestic Trading and Logistics
Company
307, 3rd Floor, Sachet-IV
Prematirth Derasar Road, Satellite
Ahmedabad, Gujarat
380 015
Tel: 91 990922377

INDIA

Mayana Enterprise
219, Shreyas Complex
Opp. Jain Derasar, Navranpura
Ahmedabad, Gujarat
India 380009
Tel: +91 079 36421752

INDIA

Iris Healthcare Technologies Pvt Ltd
No. 15 2nd Street
JD Durairaj Nagar
Chennai, Aminijikarai
India 600029
Tel: 91 22 66066000

INDIA

Inspira Enterprise India Pvt. Ltd.
Unit No. 21, Building No. 2,
Geeta Udyog Nagar,
Near Range Office, Gokhivare
Vasai East, Thans
Inida 401 205
Tel: +91 22 40569999

INDONESIA

Transmedic Pte Ltd.
5, Jalan Kilang Barat
9th Floor Petro Centre
Singapore 159349
Tel: +65 6 7371 945

JAPAN

FUSO Pharmaceutical Industries, Ltd.
2-3-11, Morinomiya Joto-KU
Osaka 536-8523
Japan
Tel: +81 6696 91131

JAPAN

Abbott Japan
ADD Japan
3-5-27, Mita, Minato-ku
Tokyo 108-6305
Japan

KAZAKHSTAN

LLP Med Market Expert
Sarayshk Str. 56/1
Kazakhstan, Uralsk
Tel: 7-7112-500-480

KYRGYZSTAN

Meditek Ltd.
Ryskulova Str. 12
Bishkek, Kyrgyzstan 720001
Tel.: 00996 312 93 50 05

MALAYSIA

Transmedic Pte Ltd.
5, Jalan Kilang Barat
9th Floor Petro Centre
Singapore 159349
Tel: +65 6 7371 945

NEW ZEALAND

Abbott New Zealand
Building D, 4 Pacific Rise
Mt. Wellington
Auckland 1060
New Zealand
Tel: 64 9 573 6030

PAKISTAN

Hospital Supply Corporation
42 Darul Aman Society
Sharah-E-Faisal
Karachi, Pakistan 75350
Tel.: +92213403170-72
     +92300824635

PHILIPPINES

Transmedic Pte Ltd.
5, Jalan Kilang Barat
9th Floor Petro Centre
Singapore 159349
Tel: +65 6 7371 945

PHILIPPINES

Euromed Laboratories Phil, Inc.
Daang Balite, Brgy. Lalaan 1st
Silang, Cavite
4118 Philippines
Tel.: 632-524-0091

SINGAPORE

Transmedic Pte Ltd.
5, Jalan Kilang Barat
9th Floor Petro Centre
Singapore 159349
Tel: +65 6 7371 945

SOUTH KOREA

POC Korea Ltd.
Suite 1106
165 Gasan digital 2-ro, Gumchon-gu
Seoul 8504
South Korea
Tel: +82 2 2058 0971

SRI LANKA

Hemas Surgicals & Diagnostics Pvt. Ltd
439 Galle Road Colombo 3
Colombo, Sri Lanka
Tel: 94114766680

TAIWAN

Evermedical Co., Ltd.
8F. No. 369, Fuxing N. Rd.
Songshan Dist
Taipei City 105
Taiwan
Tel: +886 2 2712 6611

TAIWAN

TBMS International Corporation
4F. No. 8, Alley 30, Lane 358
Rueiguang Road, Neihu District
Taipei, 11492 Taiwan
Tel: 02-87977755

THAILAND

Transmedic Pte Ltd.
5, Jalan Kilang Barat
9th Floor Petro Centre
Singapore 159349
Tel: +65 6 7371 945

VIETNAM

Transmedic Pte Ltd.
5, Jalan Kilang Barat
9th Floor Petro Centre
Singapore 159349
Tel: +65 6 7371 945

CHINA

Bioman Technology
Room 2301-2302 East Tower
Huapu Plaza, No.13, Huaming Road
Zhujiangxincheng, Guangzhou, 510623
Peoples Republic of China
Tel.No: +86 20 288 65 008

AnHui Healthcare Medical Technology Co., Ltd.
15#, Red Maple Road
Hi-tech Zone
Hefei, Anjui, 230088, China
Tel.No: 0551-5310478

Wuhan A Bo Te Technology & Trading Co., Ltd
No.465, Luoshi Road (South)
Hongshan District
Wuhan, Hubei, 430071, China
Tel.No: 86-27-87399981

Beijing Huiwen Yuanmei Technology & Trading Co., Ltd
4D No. 1 Building, Third Department
GuangLian Industrial Park,No. 2 Kechuang
Dongwu Street, Light Mechanical and Electrical
Integration Base, TongZhou
Zhongguancun Science and Technology Park
TongZhou District, Beijing, 100111, P. R. China
Tel.No: 010-57621837 / 010-57621838

Beijing Beiyi Pharmaceuticals Co., Ltd
17-1701 Floor Founder Int'l Bldg
No 52 West Rd N4 Ring Rd
Beijing China 100080
Tel.No: 86-10-51721328

Xinijiang Yi Xun Trading Co. Ltd.
Xinijiang Urumqi City
Beijing South Road No 556
Beijing Huajie A-room
Urumqi, China 830011
Tel.: 138-0994-7966

Shanghai Runda Medical Technology Co., Ltd.
Room D, 15Fl, No.58
Xiangcheng Road, Pudong New Area District
Shanghai, 200125
China
Tel.No: 86-21-50817881

Beijing Biochem Hengye Science & Technology Development
Room 2111, No.1 Kun Tai International Plaza
Chao Wai Street Yi 12
Chaoyang District, Beijing 100020
P. R. China
Tel.No: 86-01-58797798

Shenzhen Reclaim Industry Development Co., Ltd
Unit 702, 7/F, Gold Card Tech.
No.9 Gaoxin South 5 Road
Shenzhen, China 518000
Tel.No: 86-755-82311378 ext.8316

Eternal Asia Supply Chain Management Ltd.
27th Floor
Shennan Zhong Rd.
3039
Shenzhen, Guangdong
China 518033
Tel. No.: 0991 8879910

Guangdon Biochem Healthcare Investment Co., Ltd
Room 2103 A No. 263
Shuangcheng International Plaza
Hua sui Street
Tian He District
Guangzhou, China

Shanghai Cheng Pei Medicine & Technology Company Ltd
Unit 202, 2F, No. 55
1000 nong, Qianhui Rd.
Shanghai, China
Tel.No: 021 20946350

Chengdu Yuanhehuasheng Technology
Besen Beilu Rd No 5
Xicun Building F17
Chengdu City, Schhuan, China
610074
Tel.No: 028 87368899

Chongqing Chenjie Medical Equipment Co. Ltd
Room 406, Building 4
No 101 Cuibai Rd
Dadulou District
Chongqing, 400080 China
Tel.No: 2368153833

Guangzhou Anxun Biological Tech Co Ltd
228, 338 Rm Baiyn Avenue North No 1392
Guangzhou, 510440 China
Tel.No: 020 37353610

Xuzhou Ruida Medical Equipment Ltd
No. 25 Jin Qiao Road Jinshan Bridge
Economic Development Zone, XuZhou
XuZhou, Jiangsu 221005
China
Tel.No: +86 0516-8773866

Beijing Jingfatou Ruide Medical Science Technologies Co., Ltd.
Chang Xindian, XinZhuang Village NO. 50
Ninth house lease compound
South four row 1
Fengtai District t
Beijing, China 10074
Tel.No: 8610-83989917

Shenzhen Junho Technology Co., Ltd
Room 11A, Tower A, Indo Building,
Zhi chun Road A48, Haidan District
Beijing, 100098 P.R.C. 518000
Tel. No: 0755-86316515

Wuhan ZhongJi Scientific Instruments Co., Ltd.
East Lake Development Zone
Hi tech four road
Consumer Electronics Industrial Park 1
Building 1, Unit 3, Floor A3-5
Wuhan, Hubei
430060 China
Tel. No: 027-88925558

EUROPE

ARMENIA
Advanced Medical Technologies & Service (AMTS)
Saburtalo Str. 7, Flat 13
Tbilisi 0159
Georgian Republic
Tel.No.: +995 32 532 032/036

AUSTRIA
Abbott Austria
Perfektastr., 84A A-1230
Wien, Austria
A 1230
Tel. No.: +43 1 891220

AZERBAIJAN
Advanced Medical Technologies & Service (AMTS)
Saburtalo Str. 7, Flat 13
Tbilisi 0159
Georgian Republic
Tel.No.: +995 32 532 032/036

AZERBAIJAN
Albatros Heltkeyr
6 Yu. Guseinov Str.
Baku, Azerbaijan AZ1021
Tel.No: +994125648635

BELARUS
Baltas Pharma OU
Tallinn, Harjumaa
Rae vlad, Veldi tee 2
Tallinn, 75325 Estonia
Tel. No.: +375296800008

BELGIUM & LUXEMBOURG
Abbott Belgium
Abbott sa/nv
Avenue Einstein 14
1300 Wavre
Belgium
Tel.No.: +32 10 47 53 11

BOSNIA-HERZ.
Mark Medical S.P.A.
Via San Michele 334
34170 Gorizia
Italy
Tel.No.: +39 0481 21711

CROATIA
Mark Medical S.P.A.
Via San Michele 334
34170 Gorizia
Italy
Tel.No.: +39 0481 21711

CZECH REPUBLIC
Coro Medical S.R.O
Biskupsky dvur 2095/8
Prague, Czech Republic 110 00
Tel.No.: +0042603229000

DENMARK
Abbott Denmark
ADD Denmark Abbott Laboratories A/S
Emdrupvej 28C
DK-2100
Copenhagen, Denmark

FINLAND
Abbott Finland
ADD Finland Abbott Oy
Pihatörmä 1 B
ESPOO, Finland 2240

FRANCE
Abbott France
Diagnostic Division
12 Rue de la Couture
Silic 203
94518 Rungis Cedex
France
Tel. No.: +33 1 4560 2500

GEORGIA
Advanced Medical Technologies & Service (AMTS)
Saburtalo Str. 7, Flat 13
Tbilisi 0159
Georgian Republic
Tel.No.: +995 32 532 032/036

GERMANY
Abbott Germany
Max-Planck-Ring 2
D-65205 Wiesbaden – Delkenheim
Germany
Tel.No.: +49 6122 580

GERMANY
Axonlab AG
Taefernstrasse 15
Baden-Daetwil
CH 5405 Switzerland
Tel.No.: +41 56 484 8080

GREECE
Santair
Agamemnonos 41
Dafni
Athens, 17235
Greece
Tel.No.: +30 6977 61 48 77

GREECE, CYPRUS, ALBANIA AND KOSOVO
Pegasus Health and Sciences S.A.
29 Pentelis Avenue & Achileos 2
Vrilissia, Athens, Greece 15235
Tel.No.: +30 210 6139496

IRELAND
Abbott Ireland
ADD Ireland
4051 Citywest Business Campus
Kingswood Drive Tallaght.
Dublin, Ireland

ITALY
Burke & Burke
Via A. Einstein, 32
20090 ASSAGO (MI)
Italy
Tel.No.: +39 (02) 457 13 663

ITALY
Abbott Italy
Abbott S U A
Via Amsterdam 125
Rome, Italy 144

LATVIA, LITHUANIA AND ESTONIA
Alfa Laboratorija
Ieriku STR 43-25
Riga, Latvia
Tel.No.: 00371 29125199

NETHERLANDS
Abbott Netherlands
Abbott B.V.
Wegalaan 9
2132 JD Hofddorp
Netherlands
Tel.No.: +31 88 82 22 500

NORWAY
Abbott Norway
ADD Norway
Martin Linges vei 25
Postboks 1 Fornebu N-1330
Norway

POLAND
Dutchmed PL AP.z.o.o
Ul. Szajnochy 14
Bydgoszcz
Poland 85-738
Tel. No.: +48 52 345 31 15

PORTUGAL
Magnamed
Rua Prof Francisco Gentil n° 22F
2620-097 Póvoa de Santo Adrião
Portugal
Tel.No.: +351 21 938 32 40

ROMANIA
Ducos Trading Ltd
157B Barbu Vacarescu Street
1st Floor, 2nd District
Bucharest, 20276 Romania
Tel.No: 10314381094

RUSSIA
Servis Instrument LLC
1st Krasnoselsky Lane
Building 5, 1, Room 2
Moscow 107140
Russia
Tel.No.: +7 495 628 7845

RUSSIA
Nearmedic Plus LLC
Aviakonstruktora Mikoyan 12
Moscow, Russia 125252
Tel. No.: +7 (985) 222-41-87

RUSSIA
Technoproject Ltd.
Boytsova per, 4
Saint Petersburg, Russia 190068
Tel. No.: +78122729787

SCOTLAND
Point of Care Testing Ltd
Units 1-7 Arbroath Business
Denis Road
Arbroath, Angus
DD11 1RS
Scotland
Tel. No.: +44 (0) 1241 439 020

SLOVENIA
Mark Medical S.P.A.
Via San Michele 334
34170 Gorizia
Italy
Tel.No.: +39 0481 21711

SLOVENIA, CROATIA, BOSNIA SERBIA AND MONTENEGRO
EUROMED, Franci Zore s.p.
Borovec 18
Trzin, Ljubijana, Slovenia SI-1236
Tel.No.: +386 1 831 47 78

SPAIN
Ven Bios
Rua Prof Francisco Gentil n° 22F
2620-097 Póvoa de Santo Adrião
Portugal
Tel.No.: +351 21 938 32 40

SWEDEN
Abbott Sweden-Diagnostic Division
Hemvärnsgatan 9
Box 1498
Solna 171 54
Sweden
Tel. No.: +46 8 546 56 789
E.post: Service@abbott.se

SWITZERLAND
Axonlab AG
Taefernstrasse 15
CH-5405 Baden-Daetwil
Switzerland
Tel.No.: +41 56 484 8080

SWITZERLAND
Abbott Switzerland
ADD Switzerland
Neuhofstrasse 23
CH-6341 Baar
Switzerland

TURKEY
ATS Biomedekal San. Ve Tic. Ltd. Sti
Mutlukent Mahallesi
Dalaman Sokak No. 10, 06800
Beysukent
Ankara-Turkey
Tel. No.: +90 312 3875153

TURKEY
Dirim Tip Ozel Saglik
Urunleri San. Ve Tic. Ltd Sti
Sogukkuyu Mah.
Sugukkuyu Cad No: 44/1
Osmangazi
Bursa, Turkey
Tel. No.: 0090 554 593 2692

TURKEY
Gazi Kimya Tip Teknolojileri
San. Ve Tic. Anonim Sirketi
Ataturk Mahallesi Gulay Sokak No. 13/A
34758 Atasehir
Istanbul, Turkey
Tel. No.: 0090 532 462 55 69

TURKEY
Laborsan Laboratuar Tibbi Cihazlar ve Malzemeler Ticaret
Sanayii Mahallesi Kozah Sokak
No: 10/B ic Kapi No: 36, izmit
Kocaeli, Turkey
Tel. No.: 0090 532 456 48 80

TURKEY
Ozem Tibbi Cihazlar Ve Aletleri
Gida Turizm Petrol
Yunus Emre mh. 6452 sk. No: 5
Denizli, Turkey
Tel. No.: 0090 532 766 5879

TURKEY
Yetki Medikal Ltd Sti
Merkez Mah. Gulce Sok.
Girgin Ishani Kat: 1
No: 1 Kozlu
Zonguldak, Turkey
Tel. No.: 0090 532 293 22 01

UKRAINE
Intersystem LLC
Komsomolskaya str. 18
Chernigov, Ukraine 14000
Tel.: +38-0462-678-698

UNITED KINGDOM
Abbott UK
Abbott House
Vanwall Business Park, Vanwall Road
Maidenhead, Berkshire
SL6 4XF, United Kingdom
Tel.: +44 16 28 784 041

UNITED KINGDOM
Point of Care Testing Ltd
Units 1-7 Arbroath Business
Denis Road
Arbroath, Angus
DD11 1RS
UK
Tel. No.: +44 (0) 1241 439 020

WALES
Point of Care Testing Ltd
Units 1-7 Arbroath Business
Denis Road
Arbroath, Angus
DD11 1RS
Wales
Tel. No.: +44 (0) 1241 439 020

Art: 716144-00AD

Rev. Date: 16-Jan-17

LATIN AMERICA

ANTIGUA
American Hospital Supply (AHS)
1060 Maitland Center Commons
Maitland, FL USA 32751
Tel.: 407 475 1168

ARGENTINA
Drogueria Artigas S.A.
Av. Jose Luis Chorroarin, 1079
Buenos Aires Capital Federal
Argentina C1427CXH
Tel.: +64 3 338 0999

BAHAMAS
American Hospital Supply (AHS)
1060 Maitland Center Commons
Maitland, FL USA 32751
Tel.: 407 475 1168

BARBADOS
American Hospital Supply (AHS)
1060 Maitland Center Commons
Maitland, FL USA 32751
Tel.: 407 475 1168

BELIZE
American Hospital Supply (AHS)
1060 Maitland Center Commons
Maitland, FL USA 32751
Tel.: 407 475 1168

BOLIVIA
Sanimed, S.R.L.
Calle Cordero No 130
Zona San Jorge
La Paz, Bolivia
Tel.: (591-2) 2431294

BONAIRE
American Hospital Supply (AHS)
1060 Maitland Center Commons
Maitland, FL USA 32751
Tel.: 407 475 1168

BRAZIL
Tecno4 Produtos Hospitalares Ltda.
Rua Backer
89 Cambuci
Sao Paulo
Brazil 01541-000
Tel.: +1 55 11 95557-6345

BRAZIL
Promedica Produtos Hospitalares Ltda.
Rua Conde de Porto
Alegre, 57 1°
Andar Rocha
Rio de Janeiro
Brazil 20960-110
Tel.: +1 55 21 7818-0462

BRAZIL
PMH Produtos Medicos Hospitalares LTDA
SIA Trecho
17 RUA 8 LOTE 170
Brasilia, DF Brazil 71200-222
Tel.: +55 61 81312112

BRAZIL
Abbott Brazil
Rua Michigan 735 - Brooklin
Sao Paulo, Brazil 04566-905

BRAZIL
Provomendo
Rua Ruy Porto 50 loja G
Barra da Tijuca
Rio de Janeiro, RJ 22793-077
Brazil
Tel.: 55 21 24860161

BRAZIL
Seventh Medical
Avenida Cosme Ferreira 1877
Manaus, Amazonas
69083-000 Brazil
Tel.: +5592 21264000

CAYMANS
American Hospital Supply (AHS)
1060 Maitland Center Commons
Maitland, FL USA 32751
Tel.: 407 475 1168

CHILE
Alatheia
Avenida del Valle Norte 945
Oficina 5610
Huechuraba, Santiago
Chile
Tel.: +562 343 5122

COLOMBIA
Arrow Medical SAS
Calle 23 # 43 A-100
Medellin, Antioquia
Colombia
Tel.: +574 356 1111

COSTA RICA
Tri-Dm
75 Oeste de la Cruz Roja costarricense
Cs 16 a 18-Av.8
Edificio 1628
San Jose, Costa Rica
Tel.: +506 2257 7676

CURACAO
American Hospital Supply (AHS)
1060 Maitland Center Commons
Maitland, FL USA 32751
Tel.: 407 475 1168

DOMINICA
American Hospital Supply (AHS)
1060 Maitland Center Commons
Maitland, FL USA 32751
Tel.: 407 475 1168

DOMINICAN REPUBLIC
American Hospital Supply (AHS)
1060 Maitland Center Commons
Maitland, FL USA 32751
Tel.: 407 475 1168

ECUADOR
M. R. U.
Fortune Plaza Medical & Business
Av. Eloy Alfaro N29-235
Entre Italia y Alemania
Piso 4.to Of. #403
Ecuador
Tel.: +593-2 3801 533

EL SALVADOR
Interserv SA de CV - El Salvador
67 Avenida Sur
Final Pasaje "A", No. 4-B
Colonia Roma
San Salvador
El Salvador Cp 1101
Tel: +503 2223-5510

GRENADA
American Hospital Supply (AHS)
1060 Maitland Center Commons
Maitland, FL USA 32751
Tel.: 407 475 1168

HONDURAS
ProdyLab S de R.L.
Bo. Guamilito, Edificio Plaza Guamilito
Local No. 1
8 Avenida, 4 y 5 Calle, N.O
San Pedro Sula, Cortes
Honduras
Tel: +504 2550-3091/+504 2550-3062

MEXICO
Abbott Laboratories de Mexico
Universal International Service
Calle 539 N6 UH
San Juan De Argon
07969 Mexico
Tel: +525558097632

ST. LUCIA
American Hospital Supply (AHS)
1060 Maitland Center Commons
Maitland, FL USA 32751
Tel.: 407 475 1168

TORTOLA
American Hospital Supply (AHS)
1060 Maitland Center Commons
Maitland, FL USA 32751
Tel.: 407 475 1168

PARAGUAY
INDEX S.A.C.I.
Boqueron No. 676
Postal Code 1414
Asuncion
Paraquay
Tel: 595-21-214-213

ST. MAARTEN
American Hospital Supply (AHS)
1060 Maitland Center Commons
Maitland, FL USA 32751
Tel.: 407 475 1168

TRINIDAD
American Hospital Supply (AHS)
1060 Maitland Center Commons
Maitland, FL USA 32751
Tel.: 407 475 1168

PERU
Biomedical Systems, S.A.
Av. Rafael Escardo
No. 823, San Miguel
Lima 32 , Peru
Tel: +511 241 3843

ST. VINCENT
American Hospital Supply (AHS)
1060 Maitland Center Commons
Maitland, FL USA 32751
Tel.: 407 475 1168

TURKS & CAICOS ISLANDS
American Hospital Supply (AHS)
1060 Maitland Center Commons
Maitland, FL USA 32751
Tel.: 407 475 1168

MIDDLE EAST

IRAQ
Hali Pharma
Boulevard 308 St. 23 Building 17 Al Raid
District
Baghdad, Iraq
Tel: +201003333444

KINGDOM OF BAHRAIN
Gulf Corporation for Technology
Bldg 2038, Road: 4156, Block: 341
Manama/Al Juffair
Kingdom of Bahrain
Tel: 97317240597

OMAN
Waleed Pharmacy & Stores LLC
Street No. 40, Building No. 176
North Al Ghoubra, Ministry Road
Ghoubra Roundabout, P.O. Box 437
Sultanate of Oman
Muscat 100 Oman
Tel: 96899338480

U.A.E.
Gulf and World Traders
P.O. Box 5527, Al Garhoud Area
Opposite DHL Office
Dubai
U.A.E.
Tel.No.: +971 4 2821717

ISRAEL
Getter Bio-Med
7th Shimson St.
Kiryat-Arie, Petach-Tikva
Israel, 49517
Tel: 972-3-5761515/625

KUWAIT
Bader Sultan & Bros. W.L.L.
Block B 67, Shuwaikh, Future Zone
P.O. Box: 867 Safat
13009 Safat
Kuwait
Tel: +965 2461 0280

QATAR
Khalid Scientific Company W.L.L.
Sheikh Khalid Building
Gulf Street
P.O. Box 4349
Doha
Qatar
Tel: +974 432 5198 / 441 7471 /
442 7784 / 431 2233

YEMEN
Griffin Ltd.
Near Linton R/A 13
Opposite Mineral Circles
Bearing Free St.
Jebel Ali, 732 UAE
Tel. No.: +967 1 441 907

JORDAN
Smart Care Medical Co.
Wasfi El tall street
al Fannar complex
Amman, Jordan
Tel: 1 55 11 95557-6345

LEBANON
Union Pharmatique d Orient
Museum Street Badaro
Beirut 11-0709
Lebanon
Tel: +96 113 87815

SAUDI ARABIA
**Medical Supplies & Services Co. Ltd
(MEDISERV)**
Mediserv Building
Alahassa Street
Riyadh, Saudi Arabia
Tel.No.: +966 1 478 0555

Art: 716144-00AD
Rev. Date: 16-Jan-17

i-STAT® TECHNICAL BULLETIN

OCTOBER 2007 UPDATE TO THE i-STAT CENTRAL DATA STATION VERSION 5

MONITORS

A new Alarm Monitor has been added which displays real time alerts and conditions of the system that require attention. This initial release activates a set of alarms related to analyzers not being able to update CLEWs, software binaries, or customization preferences.

To access this new Monitor, click on **Main** → **Open Monitor** → **Alarm** from the menu bar or **Alarm Monitor** from the Monitor submenu toolbar. A window will open listing the currently enabled alarm categories and how many total alarms have been detected from each category. A date/time stamp indicating when the monitor was last updated is also visible to the lower left corner of the list.

Category	Total Alarms
CLEW update failure	29
Preferences update failure	32
Analyzer transmission failure	10
Database file error	4

Monitor last updated: 30Aug2007 09:47

Clicking on an individual alarm category opens a window displaying specific details of the alarms detected in that category, the date/time they occurred, and in what location.

Selected Alarm details or all Alarm details may be deleted by clicking the Acknowledge button at the bottom of the window.

A report of selected Alarm details or all Alarm details may be printed by clicking the Print button at the bottom of the window.

The default setting for the Alarm Monitor is to have all Alarm Categories and the individual detailed alarms contained in those categories enabled. To disable alarm reporting, alarm categories, or specific alarms contained in those categories:

1. Close the CDS application, if open.

2. Click **Start → Run…**

3. Type **wcds32 config** at the **Open**: prompt and click **OK**.

4. When the i-STAT Central Data Station Customization window appears, click on the **Alarms** tab.

5. To disable alarm reporting, uncheck the "Enable alarm reporting" box and click **Accept**.
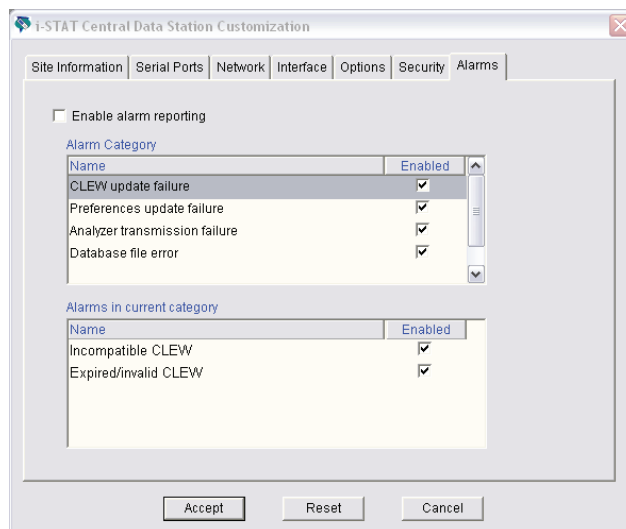
6. To disable an entire Alarm Category, uncheck the "Enabled" box next to the Alarm Category you wish to disable.
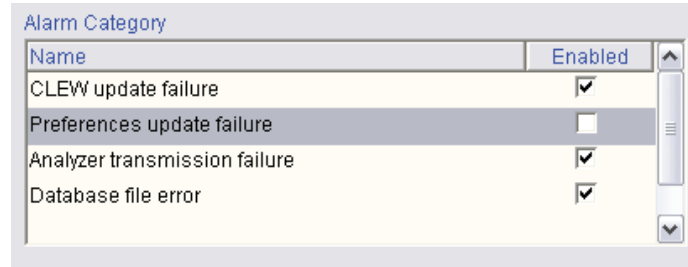
7. To disable a specific alarm contained in an Alarm Category, click the Alarm Category containing the alarm to be disabled, and then uncheck the "Enabled" box next to the alarm you wish to disable.
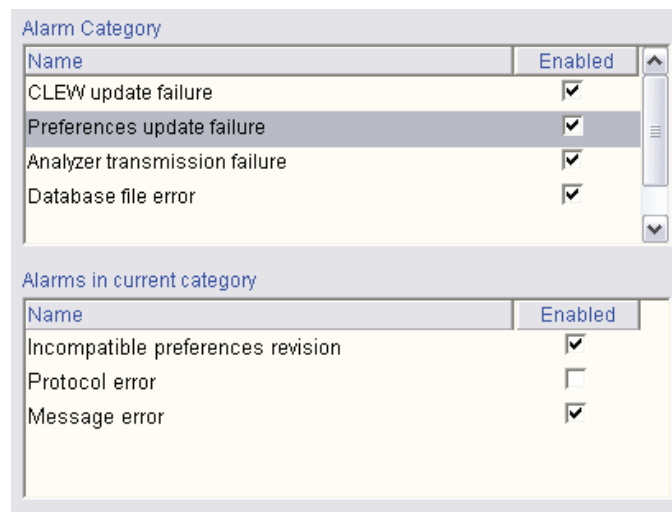
8. Once all Alarm Categories and specific alarms you do not wish to view are disabled, click **Accept**.

REPORTS

1. The Precision PCx method can now be selected on the Reagent Usage and Method Competence reports.

2. Monthly subtotals may now be included in the Reagent Usage and Method Competence reports.
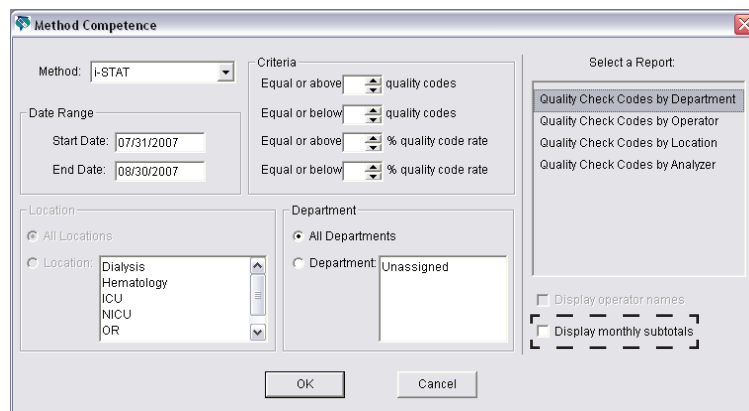
i-STAT CENTRAL DATA STATION CUSTOMIZATION

A. Results Viewer

Users now have the option to include/exclude the patient name from the trend display or printout in the Results Viewer. The default setting is to have the patient name included in the trend report.

To exclude the patient name from the trend display and printout:

1. Close the CDS application, if open.

2. Click **Start → Run…**

3. Type **wcds32 config** at the **Open**: prompt and click **OK**.

4. When the i-STAT Central Data Station Customization window appears, click on the **Options** tab.

5. Uncheck the "Show Patient Name in Trend view/print" box and click **Accept**.
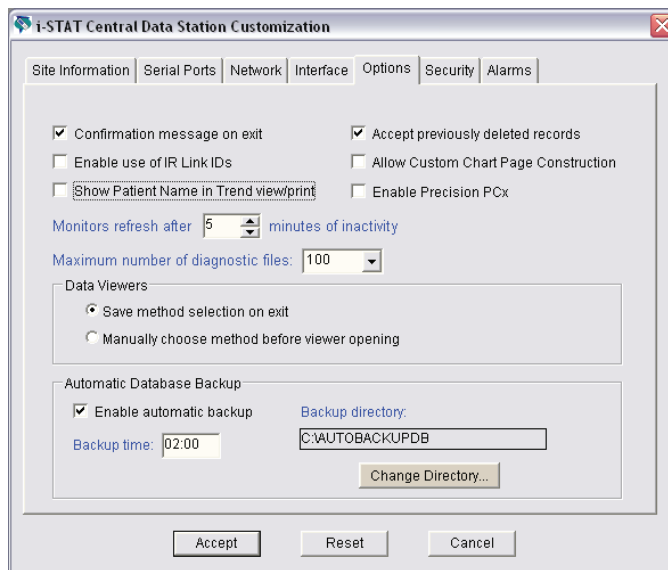
B. Enabling the Precision PCx Method

The Precision PCx method may now be enabled/disabled from the i-STAT Central Data Station Customization screen. The default is to have the Precision PCx method disabled.

To enable the Precision PCx method:

1. Close the CDS application, if open.

2. Click **Start → Run…**

3. Type **wcds32 config** at the **Open**: prompt and click **OK**.

4. When the i-STAT Central Data Station Customization window appears, click on the **Options** tab.

5. Check the "Enable Precision PCx" box and click **Accept**.
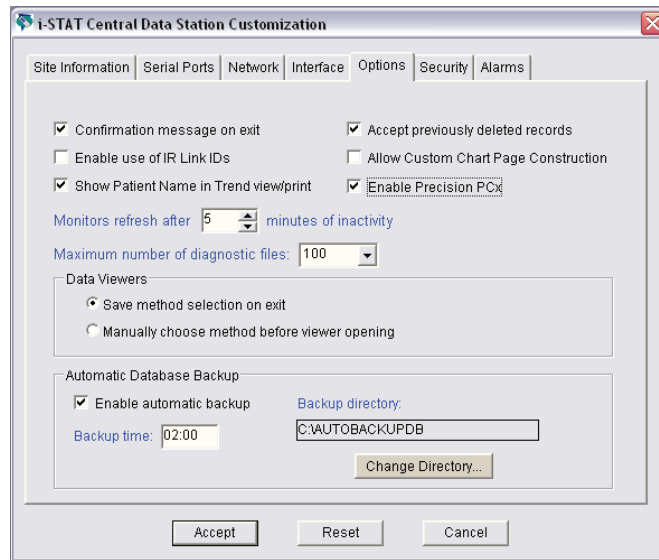
INVENTORY WORKSPACE

In the Items tab page, items can now be moved to the "Available items:" list using a drag/drop technique.

INSTRUMENT /LOCATION WORKSPACE

Instead of highlighting an instrument serial number and clicking on **Instrument → Move…** from the menu bar or **Move Inst.** in the toolbar, instruments can now be moved singly or in groups to new locations using a drag/drop technique.

Instruments may now also be deleted in groups. Simply highlight all of the instruments to be deleted and click on **Instrument → Delete…** from the menu bar or the **Delete Instrument** in the toolbar.

OPERATOR WORKSPACE

The i-STAT and Precision PCx certifications for operators may now be updated at the same time.

1. Highlight the operator to be updated and click on **Operator → Update Certification…** from the menu bar or **Update Cert.** in the toolbar.
2. Check the box next to the   method(s) for which the operator is being certified, enter the certification dates, and click **OK**.

Art: 720735-00B
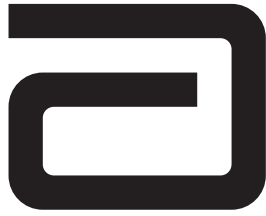
i-STAT®
TECHNICAL BULLETIN

APRIL 2008 UPDATE TO THE i-STAT CENTRAL DATA STATION VERSION 5

QUALITY CHECK CODES VIEWER

A new column has been added to the Quality Check Codes Viewer indicating the Quality Code Category corresponding to the individual quality check code.

Date - Time	Quality Code	Quality Code Category	Serial Number	Sent	Comment	Location	C
10/08/06 02:48:16	CODE 69	Other	10016	Yes		A_3	0
10/08/06 02:45:15	CODE 69	Other	10016	Yes		A_3	0
10/07/06 02:51:50	CODE 69	Other	10016	Yes		A_3	0
08/20/06 18:27:14	CODE 69	Other	12345	Yes		ER	0
08/20/06 10:14:37	CODE 69	Other	12345	Yes		ER	0
08/26/04 18:59:23	CODE 69	Other	10016	No		A_7	
08/19/04 23:56:16	CODE 1	Environment	10016	No		A_7	569
08/19/04 23:53:24	CODE 21	Cartridge Handling	10016	No		A_7	123
08/19/04 23:28:19	CODE 35	Underfilled Cartridge	10016	No		A_7	
08/19/04 23:22:31	CODE 35	Underfilled Cartridge	10016	No		A_7	123
08/19/04 23:17:51	CODE 35	Underfilled Cartridge	10016	No		A_7	123
07/31/04 20:10:44	CODE 24	Cartridge Handling	10020	No		A_7	123
07/31/04 19:57:26	CODE 24	Cartridge Handling	10020	No		A_7	123
07/27/04 12:57:08	CODE 21	Cartridge Handling	10020	No		A_7	
07/27/04 10:15:01	CODE 33	Other	10020	No		A_7	1
07/27/04 10:06:31	CODE 30	Overfilled Cartridge	10020	No		A_7	333
07/27/04 10:02:19	CODE 35	Underfilled Cartridge	10020	No		A_7	333
07/27/04 09:55:15	CODE 69	Other	10020	No		A_7	333

Abbott
Point of Care

Art: 721106-00B

i-STAT® TECHNICAL BULLETIN

APRIL 2009 UPDATE TO THE i-STAT CENTRAL DATA STATION VERSION 5

CUSTOMIZATION WORKSPACE

A new feature has been added allowing users to delete unused Preferences so that they no longer appear in the *Apply Preferences* window.

Note: the DEFAULT0 Preferences may not be deleted.

To delete unused Preferences:

1. Click **Profile → Delete Unused Preferences…** in the menu. The *Delete Preferences* window will then open.
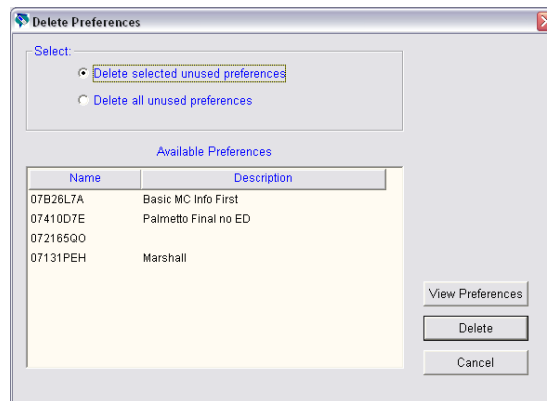
2. Users may either *Delete selected unused preferences* or *Delete all unused preferences* by clicking the appropriate radio button.

   a. To delete selected unused preferences:

   - Click the *Delete selected unused preferences* radio button.

   - In the *Available Preferences* section, click on the Name of the Preferences you wish to delete.

   - If you wish to view the contents of the selected Preferences before deleting it, click **View Preferences**.

   - Click **Delete**.

   - A confirmation message will appear asking if you want to want to delete the preferences. Click **Yes** to delete the Preferences.

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b. To delete all unused preferences:

- Click the *Delete all unused preferences* radio button.
- Click **Delete**.
- A confirmation message will appear asking if you want to delete the preferences. Click **Yes** to delete the Preferences.

DATA VIEWER

1. A new feature has been added to the Results and Proficiency Viewers allowing the ability to display/print Reference Ranges with individual results.

    Note: The Preferences associated with an individual record must be present in the Customization Workspace for this option to appear.

    To view/print Reference Ranges for a particular result record:

    - Double click on the record to be viewed/printed. The *Details* window will appear.
    - Check the *Show Reference Ranges* box in the lower left corner of the Details window.
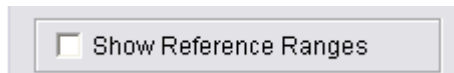
    - Two options will appear for viewing the Reference Ranges with the results
      - o *With Results*: the References Ranges will appear directly below the Test Results

      - o *Separately*: the Reference Ranges appear to the right of the Test Results in a separate box

      Note: The Reference Ranges will always print below the Test Results, whether *With Results* or *Separately* is chosen for viewing.

2. Trend displays and multi-result printouts will now not be allowed if any particular analyte in the set of analyte values is present with more than one unit.

For example, if a user wants to see a trend display or obtain a multi-result printout for a particular patient ID number, and this patient ID number has records attached with ionized calcium values in both mmol/L and mg/dL, a message will appear indicating that the display/printout will not be allowed.

STAT*Notes* (FORMERLY KNOW AS CHART PAGE CUSTOMIZATION OR PATIENT RESPIRATORY PARAMETERS (PRP))

The following information pertains to changes to the Customization feature formerly known as Chart Page Customization or Patient Respiratory Parameters (PRP). With the release of CDS Software version 5.23a, this feature will now be referred to as STAT*Notes*, All Windows texts/error messages/menus in the Customization Workspace have now been changed to accommodate this new product name. The use of the phrases "Chart Pages" or "Custom Chart" have now been replaced with "STATNotes". Below is an example of the heading changes in the main Customization Workspace screen:

Those customers already using STAT*Notes* should review the information below for new use options. Those not currently using the STAT*Notes* feature are encouraged to read the Overview section and contact their Abbott Point of Care Sales Representative for more information regarding this special customization feature.

Overview: The i-STAT 1 Handheld Chart Page was originally developed to allow a user to enter relevant patient information at the time of a patient test. Through a series of prompts, users may enter data in Field 1, Field 2, and Field 3 in order to record additional information such as respiratory parameters.

The current i-STAT 1 Handheld Chart Page can now be customized to create a STAT*Notes* page providing Data Entry items and Selection List items. Data Entry items allow a user to scan or enter alphanumeric data using the analyzer keypad. Selection List items allow a user to select from a customizable list of choices. STAT*Notes* pages can be assigned for presentation when a particular cartridge is run on a location-specific basis to provide additional flexibility in meeting each department's unique needs for data collection.

NEW STAT*Notes* FEATURES:

Applying STAT*Notes*: A new feature has been added allowing users to apply an existing STAT*Notes* to the default profile or to various locations.

To apply STAT*Notes*:

1. Click **Profile** → **Apply STAT*Notes*…** in the menu. The *Apply STAT*Notes window will then open.
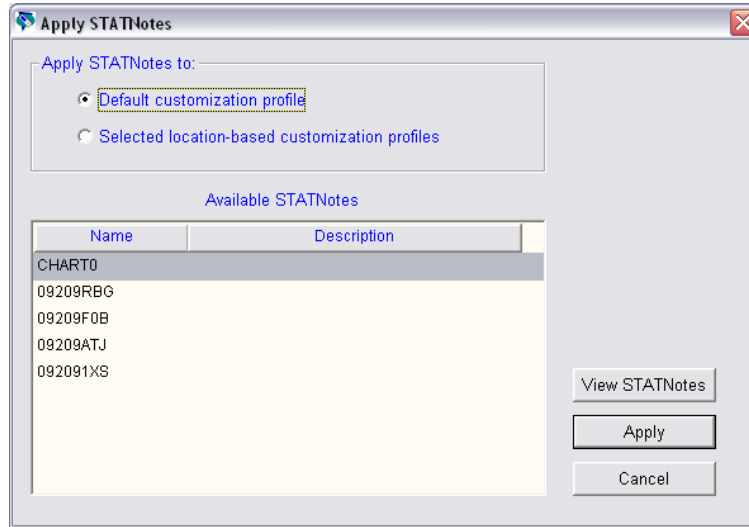
2. Users may either apply STAT*Notes* to the *Default customization profile* or to *Selected location-based customization profiles* by clicking the appropriate radio button.

   a. To apply a particular STAT*Notes* to the default customization profile:
      - Click the *Default customization profile* radio button.
      - In the *Available STAT*Notes section, click on the Name of the STAT*Notes* you wish to apply.
      - If you wish to view the contents of the selected STAT*Notes* before applying it, click on **View STATNotes**.
      - Click **Apply**
      - A confirmation message will appear asking if you want to want to proceed in changing the STAT*Notes*. Click **Yes** to apply the STAT*Notes*.

   b. To apply a particular STAT*Notes* to location-based customization profile(s):
      - Click the *Selected location-based customization profiles* radio button.
      - In the *Available STAT*Notes section, click on the Name of the STAT*Notes* you wish to apply.
      - If you wish to view the contents of the selected STAT*Notes* before applying it, click **View STATNotes**.
      - Click **Apply**
      - A confirmation message will appear asking if you want to proceed in changing the STAT*Notes*. Click **Yes** to apply the STAT*Notes* to selected locations in the Customization Workspace.

Deleting STAT*Notes*: A new feature has been added allowing users to delete unused STAT*Notes* so that they no longer appear in the *Apply STAT*Notes window.

To delete unused STAT*Notes*:

1. Click **Profile → Delete Unused STATNotes…** in the menu. The *Delete STAT*Notes window will then open.
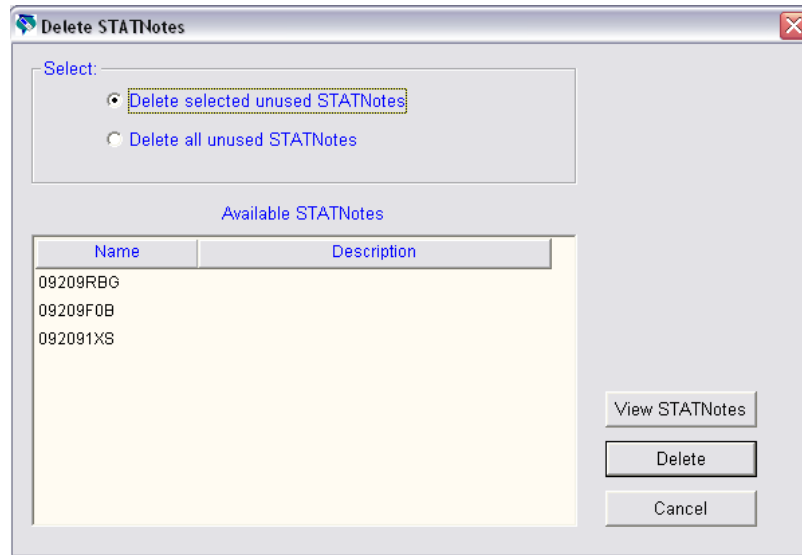
2. Users may either *Delete selected unused STAT*Notes or *Delete all unused STAT*Notes by clicking the appropriate radio button.

   a. To delete selected unused STAT*Notes*:
      - Click the *Delete selected unused STAT*Notes radio button.
      - In the *Available STAT*Notes section, click on the Name of the STAT*Notes* you wish to delete.
      - If you wish to view the contents of the selected STAT*Notes* before deleting it, click **View STATNotes.** Otherwise, click **Delete**.
      - A confirmation message will appear asking if you want to want to delete the STAT*Notes*. Click **Yes** to delete the STAT*Notes*.

   b. To delete all unused STAT*Notes*:
      - Click the *Delete all unused STAT*Notes radio button.
      - Click **Delete**.
      - A confirmation message will appear asking if you want to delete the STAT*Notes*. Click **Yes** to delete all the STAT*Notes*.

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i-STAT® TECHNICAL BULLETIN

APRIL 2009 UPDATE TO i-STAT/DE (VERSION 2.0)

DO NOT INSTALL i-STAT/DE WITHOUT FIRST CONSULTING YOUR DATA MANAGEMENT VENDOR

Important: Do not update to a new version of i-STAT/DE without first contacting your data management vendor. It is important that data management vendors be involved in the updates because:

1. Your data manager must first validate the new version of i-STAT/DE for use with their system. This can take some time after Abbott Point of Care releases a new version of i-STAT/DE.

2. Restart of their systems may be required to resume processing data after an update to i-STAT/DE.

3. DO NOT upload the i-STAT/DE update file to the i-STAT/DE server if you do not wish to immediately update i-STAT/DE.

ABBOTT DIABETES CARE PrecisionWeb USERS:

Please contact ADC Technical Support. ADC will coordinate the update of i-STAT/DE with you once they have completed integration testing with PrecisionWeb.

MEDICAL AUTOMATION SYSTEMS RALS-PLUS USERS:

Please visit the Medical Automation Systems website at http://www.rals.com/istat_De_Software.html for details regarding the update of i-STAT/DE.

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APRIL 2009 UPDATE TO i-STAT/DE (VERSION 2.0)

INSTRUCTIONS FOR INSTALLATION OF i-STAT/DE VERSION 2.0

i-STAT/DE upgrades must be performed directly on the server where i-STAT/DE is installed.

1. Close all applications

2. Insert the i-STAT/DE version 2.0 CD.

3. The setup utility will automatically start. *After clicking **Yes** in the <u>OEM Software Agreement</u> dialog box, no further user intervention is required and the computer will automatically reboot when the setup utility completes*. Once the computer is rebooted, remove the CD-ROM from the drive.

PAGE LAYOUT

All pages have been modified in appearance to provide a more uniform look and feel.

CUSTOMIZATION WORKSPACE

A new feature has been added allowing users to delete unused Preferences so that they no longer appear on the *Apply Preferences* web page.

<u>Note: the DEFAULT0 Preferences may not be deleted.</u>

To delete unused Preferences:

1. Click **Preferences** → **Delete Preferences** in the menu. The *Delete Preferences* web page will then open.
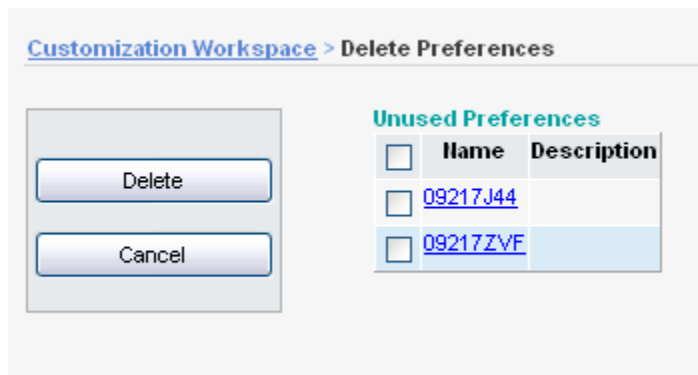
2. To delete selected Unused Preferences:

   • Check the box next to the Name(s) of the Preferences you wish to delete.

   • If you wish to view the contents of a Preferences before deleting it, click on the Preferences name.

   • Click **Delete**.

   • A confirmation message will appear asking if you want to want to delete the selected Preference set(s). Click **Yes** to delete the Preferences

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STAT*Notes* (FORMERLY KNOW AS CHART PAGE CUSTOMIZATION OR PATIENT RESPIRATORY PARAMETERS (PRP))

The following information pertains to changes to the Customization feature formerly known as Chart Page Customization or Patient Respiratory Parameters (PRP). With the release of i-STAT/DE version 2.0, this feature will now be referred to as STAT*Notes*, All texts/error messages/menus in the Customization Workspace have now been changed to accommodate this new product name. The use of the phrases "Chart Pages" or "Custom Chart" have now been replaced with "STATNotes". Below is an example of the heading changes in the main Customization Workspace screen:

Those customers already using STAT*Notes* should review the information below for new use options. Those not currently using the STAT*Notes* feature are encouraged to read the Overview section and contact their Abbott Point of Care Sales Representative for more information regarding purchase of this special customization feature.

<u>Overview</u>: The i-STAT 1 Handheld Chart Page was originally developed to allow a user to enter relevant patient information at the time of a patient test. Through a series of prompts, users may enter data in Field 1, Field 2, and Field 3 in order to record additional information such as respiratory parameters.

The current i-STAT 1 Handheld Chart Page can now be customized via i-STAT/DE to create a STAT*Notes* page providing Data Entry items and Selection List items. Data Entry items allow a user to scan or enter <u>alphanumeric data</u> using the analyzer keypad. Selection List items allow a user to <u>select from a customizable list</u> of choices. STAT*Notes* pages can be assigned for presentation when a particular cartridge is run on a location-specific basis within a facility to provide additional flexibility in meeting each department's unique needs for data collection.

NEW STAT*Notes* FEATURES:

Applying STAT*Notes*: A new feature has been added allowing users to apply an existing STAT*Notes* to the default profile or to various locations.

To apply STAT*Notes*:

1. Click **STATNotes** → **Apply STATNotes** in the menu. The *Apply STATNotes* web page will then open.

2. Users may either Apply Stat*Notes* to the *Default customization profile* or to *Selected location-based customization profiles* by clicking the appropriate radio button.

    a. To apply a particular STAT*Notes* to the default customization profile:
        *   Click the *Default customization profile* radio button.
        *   In the *Available STATNotes* section, click **Select** in the row containing the STAT*Notes* you wish to apply.
        *   If you wish to view the contents of the selected STAT*Notes* before applying it, click **View STATNotes**.
        *   Click **OK**.
        *   A confirmation message will appear asking if you want to proceed in changing the STAT*Notes*. Click **Yes** to apply the STAT*Notes*.

    b.   To apply a particular STAT*Notes* to a location-based customization profile:
        *   Click the *Selected location-based customization profiles* radio button.
        *   In the *Available STATNotes* section, click **Select** in the row containing the STAT*Notes* you wish to apply.
        *   If you wish to view the contents of the selected STAT*Notes* before applying it, click **View STATNote**s.
        *   Under the *Apply* column, check the box(es) next to the destination location(s) where the STAT*Notes* is to be applied.
        *   Click **OK**.
        *   A confirmation message will appear asking if you want to proceed in changing the STAT*Notes*. Click **Yes** to apply the STAT*Notes*

Deleting STAT*Notes*: A new feature has been added allowing users to delete unused STAT*Notes* so that they no longer appear on the *Apply STATNotes* web page.

To delete unused STAT*Notes*:

1. Click **STATNotes** → **Delete STATNotes** in the menu. The *Delete STATNotes* web page will then open.
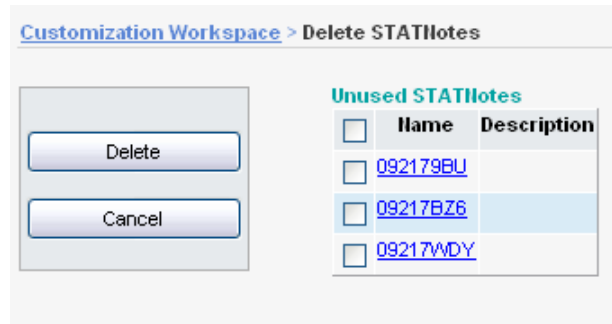
2. To delete selected unused STAT*Notes*:

    •   Check the box next to the Name(s) of the STAT*Notes* you wish to delete.
    •   If you wish to view the contents of the selected STAT*Notes* before deleting it, click on the STAT*Notes* name.
    •   Click **Delete**.
    •   A confirmation message will appear asking if you want to want to delete the selected STAT*Notes*. Click **Yes** to delete the STAT*Notes*

New Features

LOADING NEW VERSIONS OF CLEW/JAMS TO i-STAT/DE:

i-STAT/DE Version 2.0 allows future versions of i-STAT/DE (i.e. Version 2.1) and CLEW/JAMS to be be updated via the i-STAT/DE Customization Workspace pages.

This functionality is found under the new menu item *Upload Update File* on the main Customization Workspace page.

To upload a new CLEW/JAMS file:

1. Click **Update i-STAT/DE -> Upload Update File** in the menu. The *i-STAT/DE* Update web page will then open
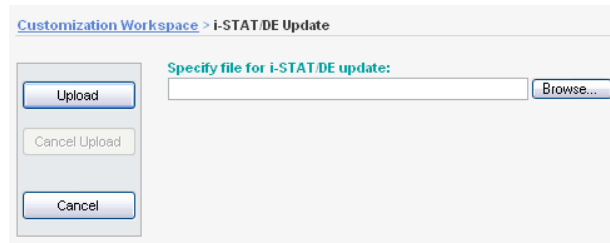
2. Browse to select the CLEW/JAMS file to be updated to the i-STAT/DE Server and click **Upload**

    a. CLEW/JAMS self extracting files for upload to i-STAT/DE are found on the i-STAT Software update CD and named as 'SUXXXXXX.exe' where XXXXXX is the JAMS and CLEW version that you are updating

    b. Immediately after uploading the CLEW/JAMS to the i-STAT/DE server, i-STAT/DE will unpack the files and make them available for use in the handheld's customization workspace.

UPLOADING NEW VERSIONS OF i-STAT/DE:

1. Click **Update i-STAT/DE -> Upload Update File** in the menu. The *i-STAT/DE Update* web page will then open.
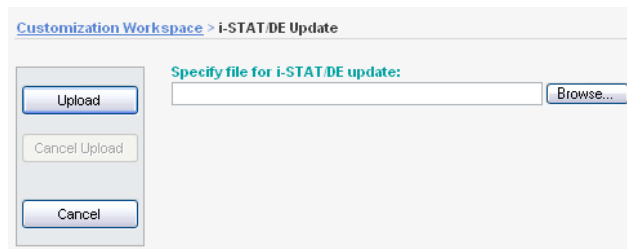
2. Browse to select the file to be uploaded to the i-STAT/DE Server and click **Upload**.

    a. i-STAT/DE self extracting files for upload to i-STAT/DE are found on the i-STAT/DE update CD.

    b. Immediately after uploading the i-STAT/DE update file to the i-STAT/DE server, i-STAT/DE will begin extracting and installing the update file.

    c. The installation process will require that i-STAT/DE be stopped temporarily while the update occurs.

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i-STAT®
TECHNICAL BULLETIN

Using i-STAT® Analyzer Customization Features to Minimize ID Entry Errors

INTRODUCTION

This Technical Bulletin describes seven i-STAT® Analyzer Customization features that can help minimize Patient and Operator ID entry errors.

ID Entry on the i-STAT System and Sources of Error

The i-STAT System offers the following options for entering Patient and Operator IDs:

- Manual ID entry using the analyzer keypad, and
- Barcode scanning using the laser barcode scanner.

As with any user-operated system, ID entry errors can occur using either of the above options. These generally occur in two ways:

1. Incorrectly entering an ID.

    - Mistyping an ID
    - Incorrectly reading an ID from a patient's wrist band
    - Entering no ID at all

2. Entering an ID that represents the wrong person (Patient or Operator).

    - Scanning the wrong barcode
    - Mistyping an ID that happens to be valid for another patient or operator

i-STAT Analyzer Customization Features Used to Minimize ID Entry Errors

The table below lists seven helpful Customization features and related information to support minimizing ID entry errors.

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Customization Feature	Technical Bulletin Section	i-STAT 1 Analyzer	i-STAT Portable Clinical Analyzer (PCA)
Barcode Scanning	Section 1	X	
Use Operator List	Section 2	X	
Excluding Operator IDs from Analyzer Printout	Section 3	X	X
Set Max/Min ID Length	Section 4	X	X
Set Manual Entry Check Digits	Section 5	X	
Force Manual Repeat ID Entry	Section 6	X	X
Force Scanned Repeat ID Entry	Section 7	X	

1. Barcode Scanning

How does this feature work? Instead of users entering Operator and Patient IDs manually using the analyzer keypad, the i-STAT 1 Analyzer also accepts scanned Operator and Patient ID information from 6 valid barcode formats.

What benefits does using barcode scanning provide?
- Using barcodes is the single most effective method of eliminating ID entry errors in the i-STAT System.

- It eliminates manual entry related errors (i.e. transposed numbers, repeated numbers, etc…).

- It provides faster ID entry.

- Customizing an analyzer to only accept a specific barcode type helps prevent users from scanning the wrong barcode type for Patient and/or Operator ID entry.

2. Use an Operator List

How does this feature work? Using an Operator List allows the Point of Care Coordinator (POCC) to maintain a list of up to 4000 operators. Each operator in the list can be certified for i-STAT and/or PCx Glucose Strip testing for a set time period defined by the POCC. Once the operator list is created, it is then uploaded to each analyzer.

What benefits does using an Operator List provide?
- It prevents uncertified or untrained operators from running tests. If the Operator List does NOT contain the ID entered by the user or if the operator is not certified, the user can be warned or locked-out from running a test.

3. Exclude Operator IDs From Analyzer Printout

How does this feature work? Enabling this feature will exclude the operator ID from all Analyzer printouts.

What benefits does this feature provide? Disabling the printing of operator IDs can help prevent uncertified operators from learning the IDs of certified operators and using those ID numbers for Analyzer testing.

4. Set Max/Min ID Length

How does this feature work? The i-STAT System provides the ability for the POCC to set minimum and maximum ID lengths. The Default Choice settings for the Operator and Patient ID lengths for each i-STAT Analyzer type are described below:

Analyzer Default Choices for ID Length		
Analyzer Type	Operator ID	Patient ID
i-STAT 1 Analyzer	0-15	0-15
i-STAT PCA	0-7	0-12

Once the POCC defines the minimum and maximum limits through customization, the analyzer will then only accept ID numbers that contain the specified number of digits.

What benefits does using Max/Min ID Length provide?
- It forces users to enter a specific ID length.

- It does NOT allow blank ID numbers when Minimum Length is set to one (1) or greater.

- It helps prevent the user from making ID entry errors such as missing digits or repeating digits.

5. Set Manual Entry Check Digits

What is a Check Digit? A Check Digit is a decimal (or alphanumeric) digit added to a number for the purpose of detecting typical data entry errors.

How does this feature work? If a facility makes use of a supported Check Digit algorithm when creating Operator or Patient IDs, the i-STAT 1 Analyzer can verify the entered ID format by calculating the check digit and comparing it to the entered ID number. If the Check Digits don't match, the ID is rejected.

Note: The i-STAT System supports the **Mod 10** and **Mod 11** check digit algorithms described in the **HL7 Table 0061** (Check Digit Scheme) in the HL7 Specification (Rev 1.4). Please contact your LIS/HIS or IT departments to help determine if your facility uses Check Digits in the creation of operator and/or patient ID numbers, and if so, what algorithm is used.

What benefits does using Manual Entry Check Digits provide? It helps prevent users from making the following ID entry errors:

- Interchanging adjacent digits (i.e. 67 becomes 76)
- Doubling the wrong digit (i.e. 445 becomes 455)
- Thinking an 8 is a 0 when reading a number from a wristband
- Omitting or adding a digit

6. Force Manual Repeat ID Entry

How does this feature work? This feature forces a user to manually enter an ID number twice. If the two entries are not identical, the ID will not be accepted and the user must start again.

What benefits does Repeat Manual ID Entry provide? The number of IDs to be corrected/edited by the POCC in the Data Management system should theoretically decrease, as a user is less likely to type an ID number wrong twice consecutively.

7. Force Scanned Repeat ID Entry

How does this feature work? This feature forces an i-STAT 1 analyzer user to scan an ID barcode number twice. If the two entries are not identical, the ID will not be accepted and the user must start again.

What benefits does Repeat Scanned ID Entry provide? The number of IDs to be corrected/edited by the POCC in the Data Management system should theoretically decrease, as a user is less likely to scan an ID number wrong twice consecutively.

NOTES:

1. Except for Operator List, all ID Entry Customization features described in this Bulletin are available on the i-STAT 1 Analyzer using:

   • Analyzer Keypad customization,
   • The i-STAT CDS Customization Workspace, or
   • Through i-STAT/DE.

   The Operator List feature is only available through the i-STAT CDS Customization Workspace or through i-STAT/DE.

   To customize for ID Entry via the i-STAT 1 analyzer keypad:

   • select **4-Customization** from the Administration Menu.
   • select **2-Change**. If the analyzer has already been customized with a password, enter the password. If not, press the Enter key. Note: Abbott Point of Care Inc. recommends changing the default password.
   • Select **2-ID Entry**, then make selections from the Customization menu.
   • After all items have been set, turn the analyzer off to save and activate the settings.

2. The individual features available on the i-STAT PCA are only available through:

   • The i-STAT CDS Customization Workspace or
   • Through i-STAT/DE.

3. Figure 1 illustrates the i-STAT Analyzer ID Entry preferences tab in the i-STAT CDS Customization Workspace. The top half of the screen lists options for entering Operator IDs and the bottom half lists options for entering Patient IDs. Individual options discussed in this Technical Bulletin are marked by numbered circles indicating the section of the Bulletin where a particular feature is described.

Figure 1

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4. Figure 2 illustrates the i-STAT CDS Customization Workspace main page.   The <u>Use Operator List feature</u>, discussed in this Technical Bulletin, is marked by the numbered circle ② indicating the section of the Bulletin where this feature is described.

Figure 2

i-STAT is a registered trademark of Abbott Laboratories.
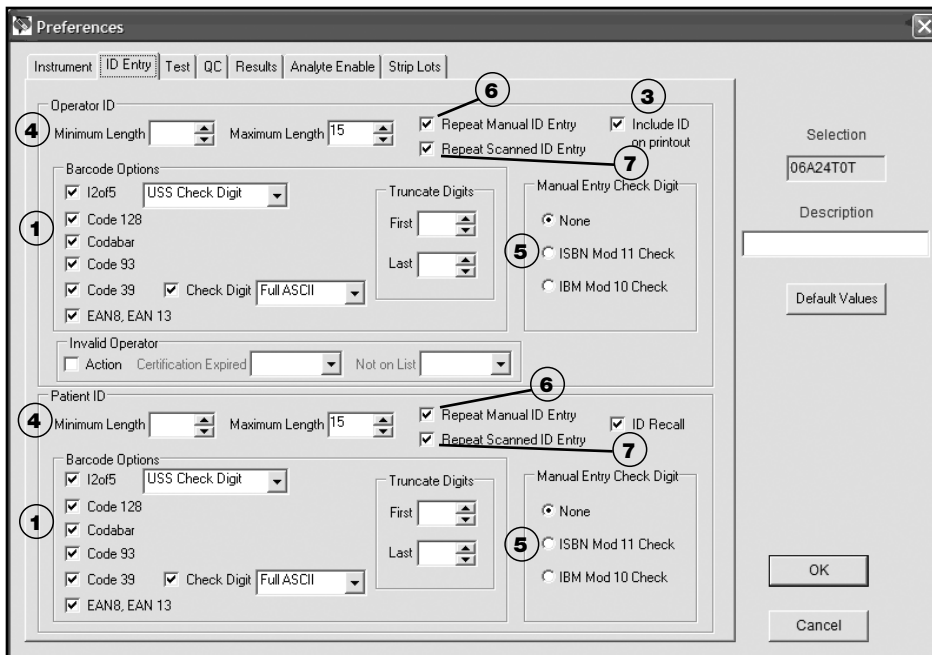
i-STAT® TECHNICAL BULLETIN

The i-STAT System Manufacturer's Quality System Instructions (for U.S.A. Laboratories only)

OVERVIEW

The Manufacturer's Quality System Instructions (MQSI) represent what are necessary to ensure quality results (accurate, precise and reliable) based upon the specific characteristics of the i-STAT System.

Three key technological characteristics of the i-STAT System underlie the MQSI:

1. The unit-use cartridges are stable when stored properly.

2. The system has been designed so that any user influence on the analytical process is detected and flagged.

3. The performance of the handheld reader is verified by a combination of automated quality checks and procedural controls during each test event, supplemented by electronic quality control.

MANUFACTURER'S QUALITY SYSTEM INSTRUCTIONS

The list below defines the i-STAT System MQSI components.

Number	MQSI Description
1	**Perform Daily Quality Control with Electronic Simulator**
	Check each Handheld reader with the Electronic Simulator, using either the internal or external simulator, once on each day of use.
2	**Check New or Replacement Handheld Readers with the Electronic Simulator**
	Use the Electronic Simulator, internal or external, to verify operation of a new or replacement handheld reader before use.
	The internal Electronic Simulator will automatically activate the first time a new or replacement handheld is used and after every 24 hours of use thereafter. The handheld can be customized to remind the operator to perform the simulator test (i-STAT Portable Clinical Analyzer and i-STAT 1 Analyzer) or automatically run the simulator (i-STAT 1 Analyzer) more frequently as required or desired.
3	**Check Temperature Strip for a New Shipment of Cartridges**
	Verify that the transit temperatures were satisfactory by reading the temperature strip included in each shipping container.

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MANUFACTURER'S QUALITY SYSTEM INSTRUCTIONS (CONTINUED)

The list below defines the i-STAT System MQSI components.

Number	MQSI Description
4	**Ensure Proper Cartridge Storage** A. Ensure that refrigerator storage conditions for stored cartridges are between 2°C – 8°C (35°F – 46°F). B. Ensure that cartridges are not exposed to temperatures exceeding 30°C (86°F). C. Ensure that cartridges are not used after the expiration date printed on the individual package and box. D. Ensure that cartridges are not outside the refrigerator for longer than the time frame indicated on the cartridge box. E. Ensure that a cartridge is used immediately after it is removed from its package. F. Ensure that a cartridge taken from refrigerated storage is allowed to stand in its package at room temperature for 5 minutes before use, or that a box of cartridges stands at room temperature for one hour before use.
5	**Ensure Thermal Probe Check is Performed** Ensure the thermal probe check is performed every 6 months on each handheld reader. This check can be performed in conjunction with the analyzer software updates.
6	**Train Staff on Avoidance of Pre- and Post-analytical Errors** Ensure that users are trained to avoid pre-analytical errors such as those associated with sample collection, delays in testing, inadequate sample mixing, and post-analytical errors (results reporting and communication).
7	**Update Software then Check with External Simulator** Update the i-STAT System software as provided by Abbott Point of Care (APOC). Check the handheld with the external Electrical Simulator after software updates. The thermal probe reading can also be taken from this check.

ADDITIONAL FDA REQUIRED ACTIVITIES FOR i-STAT WAIVED TESTS

For the i-STAT waived test cartridges, in addition to the MQSI above, the activities listed below must be conducted. These activities were required by the Food and Drug Administration (FDA) in order for APOC to obtain waived status for the cartridges.

Number	Activity Description
8	**Test Liquid Control for a New Shipment of Cartridges** Check one cartridge from each newly received lot with the appropriate i-STAT control. • CHEM8+ Cartridges: use CHEM8+ or TriControls Level 1 Control, • 6+ or Crea Cartridges: use i-STAT or TriControls Level 1 Control, • E3+, EC4+ or G Cartridges: use i-STAT or TriControls Level 3 Control.
9	**Ensure Proper Cartridge Storage (Including Monthly Check)** Verify that cartridges stored at room temperature are within expiration date and that cartridges have been out of the refrigerator less than the time frame indicated on the cartridge box. If the temperature at which cartridges are stored is in doubt, use a liquid control to verify that the cartridges are performing properly. Check storage conditions monthly by testing one cartridge from refrigerated storage with the appropriate i-STAT level control. Select the one cartridge to be tested using the following order: CHEM8+, 6+, Crea, EC4+, G, E3+. If the cartridge being tested is a: • CHEM8+ Cartridges: use CHEM8+ or TriControls Level 1 control • 6+ or Crea Cartridges: use i-STAT or TriControls Level 1 control • E3+, EC4+ or G Cartridges: use i-STAT or TriControls Level 3 control • Test the cartridge on any handheld

OTHER QUALITY CENTERED ACTIVITIES FOR ALL i-STAT TESTS

While the following are not manufacturer's quality system instructions and are not FDA required activities, they are laboratory practices centered on quality and are suggested (not required) for all i-STAT tests whether they are categorized as moderate complexity or waived.

Number	Activity Description
1	**Review Interferences with Staff**
	Review "Factors that Affect Results" listed in the Cartridge and Test Information sheets with clinical staff. Cartridge and Test Information sheets are located on the Abbott Point of Care website (www.abbottpointofcare.com/Customer-Info-Center/Cartridge-and-Test-Info-Sheets.aspx).
2	**Train Staff on Backup System Measures**
	Ensure that users are trained on the backup provisions for testing should they be unable to utilize the i-STAT System in their area.
	Backup provisions in many facilities include the use of a spare handheld reader, backup lot of cartridges, sharing of the handheld reader, or use of a laboratory system.

There may be additional Clinical Laboratory Improvement Amendments (CLIA) or accrediting organization requirements and individual state laws, codes, statutes or regulations which are not addressed in this Technical Bulletin.

i-STAT is a registered trademark of the Abbott Group of Companies in various jurisdictions.

i-STAT® TECHNICAL BULLETIN

The i-STAT System and Waived Status

OVERVIEW

The FDA has granted waived status for the following i-STAT test cartridges:

- CHEM8+ (granted September 21, 2007), and

- Crea, G, 6+, EC4+ and E3+ (granted November 13, 2008).

Waived status is applicable only when testing venous samples collected in evacuated tubes with lithium heparin (green top tubes) with any of the above listed cartridges with the i-STAT 1 Analyzer (Handheld). These new test categorizations will be listed on the CLIA database at http://www.fda.gov/cdrh/clia/ and can be found on the list of waived tests available at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfclia/testswaived.cfm.

Waived testing may be performed under all types of CLIA certificates: Certificate of Waiver (CW), Certificate of Provider-Performed Microscopy Procedures, Certificate of Compliance (COC), and a Certificate of Accreditation (COA). If you are currently maintaining a COC or COA because you are drawing venous samples collected in evacuated tubes with lithium heparin (green top tubes) and performing testing using the i-STAT CHEM8+, Crea, G, 6+, EC4+, or E3+ cartridge(s) with the i-STAT 1 Analyzer, you may "downgrade" to a CW the next time your Certificate is renewed.

THE i-STAT 1 SYSTEM MANUAL FOR WAIVED TESTS

The i-STAT 1 System Manual for Waived Tests is intended for facilities with a Certificate of Waiver. If you have a standard i-STAT System Manual and are using the i-STAT System under a Certificate of Compliance (COC) or a Certificate of Accreditation (COA), it is not necessary to order the Waived Manual. This Technical Bulletin is intended as an update to the standard i-STAT System Manuals for the use of the waived cartridges.

You do not need to have the Waived Manual if you maintain this Technical Bulletin in your current i-STAT System Manual. If desired, you can purchase the i-STAT 1 System Manual for Waived Tests (Abbott List Number 06F20-03) at no charge by contacting your Abbott Point of Care sales representative or customer service representative.

The Centers for Medicare and Medicaid Services (CMS), The Joint Commission, the College of American Pathologists, COLA and the American Association of Laboratory Accreditation (A2LA) Healthcare Facilities

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Accreditation Program (HFAP) will expect a facility to follow the instructions in the Waived Manual and summarized in this Technical Bulletin when using i-STAT waived cartridges to test venous samples as previously described. Laboratories will be expected to follow the instructions in the standard i-STAT Manual and the regulations for Moderate Complexity tests when using other i-STAT cartridges (other than CHEM8+, Crea, G, 6+, EC4+, and E3+) or if testing sample types other than venous with the CHEM8+, Crea, G, 6+, EC4+, and E3+ cartridges.

Note: If the manufacturer's instructions are not followed for any test categorization, the test defaults to high complexity.

PROFICIENCY TESTING

The Proficiency Testing Providers listed in the Technical Bulletin "Proficiency Testing and the i-STAT System," have been informed of which cartridge types have waived status. It will take time for the providers to update their survey forms.

Note that Accrediting Organizations and certain States may have additional waived testing requirements including those for the laboratory director and personnel requirements, policies and procedures, operator competency, specimen handling, results and control reporting and instrument maintenance. Some states may restrict the list of approved waived tests.

The following are **additional** manufacturer's quality system instructions for i-STAT cartridges granted waived status. A list of **all** of the manufacturer's instructions are included in both the i-STAT 1 System Manual for Waived Tests and the standard i-STAT 1 System Manual.

Additional Manufacturer's Quality System Instructions for Waived Tests	

New Shipment of Cartridges	Check one cartridge from each newly received lot with the appropriate i-STAT control:
	   • CHEM8+ Cartridges: use Tri Controls Level 1 Control,
	   • 6+ or Crea Cartridges: use i-STAT or Tri Controls Level 1 Control,
	   • E3+, EC4+ or G Cartridges: use i-STAT or Tri Controls Level 3 Control.

Ensure Proper Cartridge Storage (Including Monthly Check)	Verify that cartridges stored at room temperature are within expiration date and that cartridges have been out of the refrigerator less than the time frame indicated on the cartridge box. If the temperature at which cartridges are stored is in doubt, use a liquid control to verify that the cartridges are performing properly.
	Check storage conditions monthly by testing the one cartridge from refrigerated storage with the appropriate i-STAT level control. Select the one cartridge to be tested using the following order: CHEM8+, 6+, Creatinine, EC4+, Glucose, and E3+. If the cartridge being tested is a:
	   • CHEM8+: use Tri Controls Level 1 Control.
	   • 6+ or Crea: use i-STAT or Tri Controls Level 1 Control.
	   • E3+, EC4+ or G: use i-STAT or Tri Controls Level 3 Control.
	   • Test the cartridge on any Handheld.

Note on control testing: Cartridges and controls have been selected based on sensitivity to thermal stress. Other control levels and hematocrit controls will not enhance the detection of thermal stress and are therefore not required.

If both moderate complexity and waived tests are performed in same unit/area:

- Handhelds could be identified as "waived testing only" or "moderate complexity testing only" to make it easier to comply with the regulatory requirements;

- You still need to follow the manufacturer's requirements for the waived test(s), which include for example monthly quality control testing as outlined above, even if you decide to comply with moderate complexity requirements for the waived test(s),

CPT CODE INFORMATION

Please refer to the website www.codemap.com/abbott for the updated CPT (Current Procedural Terminology) codes for the waived cartridges.

i-STAT is a registered trademark of the Abbott Group of Companies in various jurisdictions.

i-STAT®
TECHNICAL BULLETIN

UPDATES TO THE i-STAT 1 DOWNLOADER/RE-CHARGERS

OVERVIEW

Abbott Point of Care continuously seeks to improve the reliability of our product lines. As such, we have made three (3) changes to our Downloader/Recharger products as described below.

Note: these changes do <u>not</u> impact the configuration or transmission instructions for the devices.

CHANGE DESCRIPTION
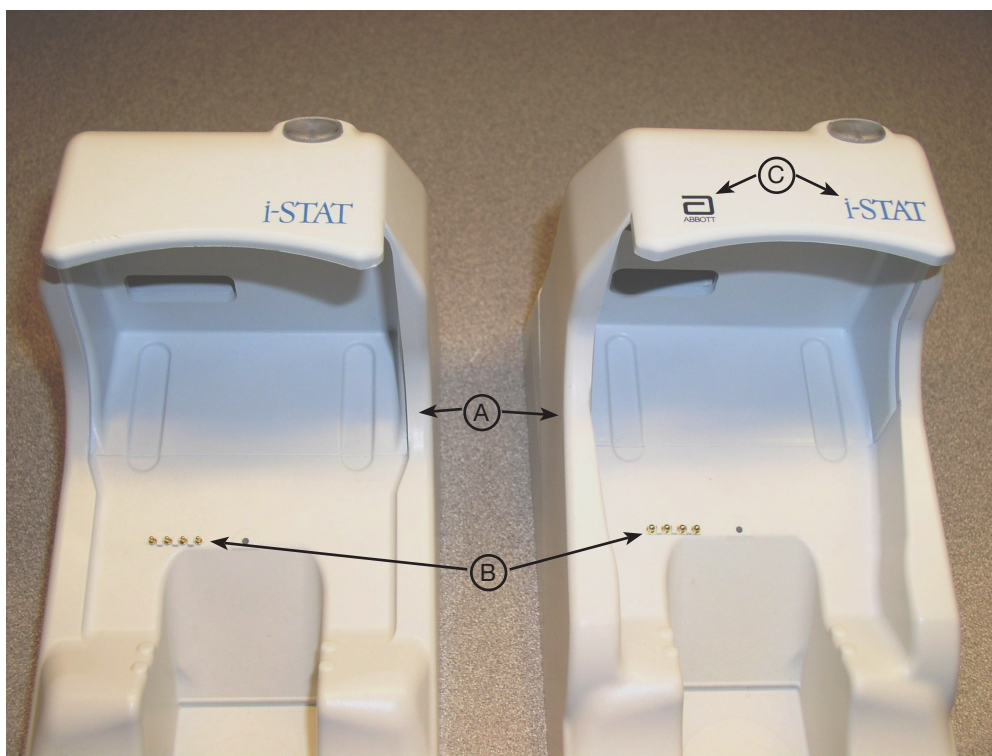
Current Downloader/Recharger   **New Downloader/Recharger**

- The side walls have been raised to prevent the insertion of a handheld at an angle or from the side. (A)
- The color of the recharge pins has been changed to silver, and their diameter has increased in size. (B)
- The front cover now has both the Abbott and i-STAT logos. (C)

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i-STAT® TECHNICAL BULLETIN

THE PRESENCE OF LATEX RUBBER IN i-STAT SYSTEM COMPONENTS

Introduction

This technical bulletin provides information on the presence of latex rubber in the components of the i-STAT® 1 and i-STAT 1 Wireless Analyzers, i-STAT Cartridges, and the i-STAT Dispensing Tip.

i-STAT 1 and i-STAT 1 Wireless Analyzers

The exterior parts of the i-STAT 1 and i-STAT 1 Wireless Analyzers are not made with natural rubber latex. No natural or synthetic rubber latex is used anywhere on the exterior of this product, the product packaging, or the accessories.

i-STAT Dispensing Tip

The components of the i-STAT Dispensing Tip are not made with natural rubber latex. No natural or synthetic rubber latex is used anywhere in this product, the product packaging, or the accessories.

i-STAT Cartridges

The large thumbwell CHEM8+, G3+, CG4+, and cTnI cartridges are not made with natural rubber latex.

The 'Sample Entry Well Gasket' contains natural rubber latex and is used on the following cartridges with the original thumbwell: EC8+, CG8+, EG7+, CHEM8+, EG6+, CG4+, 6+, G3+, EC4+, E3+, G, Crea, ACTk, ACTc, and PT/INR. The location of the 'Sample Entry Well Gasket' is shown below.

A diaphragm pump on the following cartridges (all having the original thumbwell) contains natural rubber latex: cTnI, CK-MB, β-hCG and BNP. The location of the diaphragm pump is shown below.
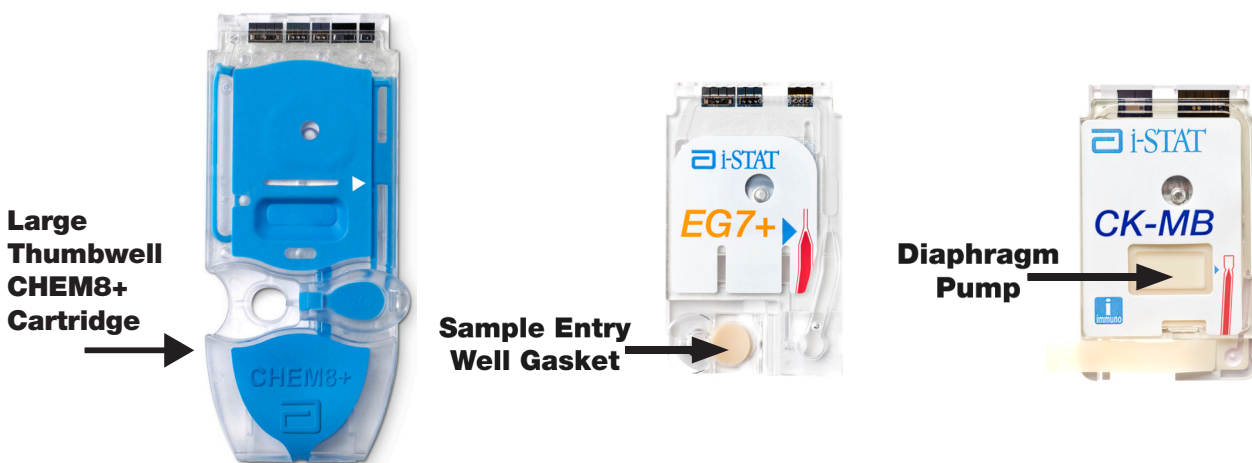
Large Thumbwell CHEM8+ Cartridge → CHEM8+

Sample Entry Well Gasket → EG7+

Diaphragm Pump → CK-MB

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Abbott Point of Care

Procedure Manual
for the i-STAT® System

This Procedure Manual is intended to be a template for the Procedure Manual required by CLIA and laboratory accreditation bodies. This Procedure Manual should be customized for site-specific policies and procedures. This Procedure Manual is not intended to replace the System Manual.

CONTENTS

SYSTEM OVERVIEW

The i-STAT System incorporates comprehensive components needed to perform blood analysis at the point of care. The system consists of the following primary components:

i-STAT 1 Analyzer

When a sample-filled i-STAT cartridge is inserted into the i-STAT 1 handheld for analysis, the handheld automatically controls all functions of the testing cycle, including fluid movement within the cartridge, calibration, and continuous quality monitoring.

Analysis Time

❑ ACT cartridge: to detection of end point – up to 1000 sec (16.7 min)

❑ PT/INR cartridge: to detection of end point – up to 300 sec (5 min)

❑ cTn, BNP, and Total β-hCG cartridges: 600 sec (10 min)

❑ CK-MB Cartridge: 300 sec (5 min)

❑ Other cartridges: typically 130 to 200 sec

Cartridges

A single-use disposable cartridge contains micro-fabricated sensors, a calibrant solution, fluidics system, and a waste chamber. Sensors for analysis of pH, $P\text{CO}_2$, $P\text{O}_2$, TCO_2, sodium, potassium, chloride, ionized calcium, glucose, lactate, creatinine, urea nitrogen (BUN) and hematocrit are available in a variety of panel configurations. Cartridges are also available for Celite-ACT, Kaolin-ACT, PT/INR, Troponin I/cTnI, CK-MB, BNP, and Total β-hCG (Table 1). A whole-blood sample of approximately 1 to 3 drops is dispensed into the cartridge sample well, and the sample well is sealed before inserting it into the analyzer.

Central Data Station or Data Manager

A dedicated desktop computer with the i-STAT Central Data Station application provides the primary information management capabilities for the i-STAT System. Downloaders and Downloader/Rechargers for the i-STAT 1 Analyzer allow for transmission of patient records from a widely distributed network of handhelds to the Central Data Station application. Data can be stored, organized, edited, and transferred to a laboratory information system or other computer system. Cartridge usage and efficiency reports can be generated for management of the system.

SUPPLIES and STORAGE REQUIREMENTS

Cartridges

Cartridges are sealed in individual pouches or portion packs. Store the main supply of cartridges at a temperature between 2 and 8 °C (35 to 46 °F). **Do not allow cartridges to freeze.** Cartridges may be stored at room temperature (18 to 30 °C, or 64 to 86 °F) for the time frame indicated on the cartridge box. Cartridges should not be returned to the refrigerator once they have been at room temperature, and they should not be exposed to temperatures above 30 °C (86 °F). If the pouch has been punctured, the cartridge should not be used. Write the date on the cartridge box or individual cartridge pouches to indicate the room temperature expiration date. Cartridges should remain in pouches until the time of use. Do not use after the labeled expiration date.

Note: See the *Check Temperature Monitor* section for information regarding the four-window temperature indicator included with cartridges for transit.

Controls

i-STAT Controls and i-STAT TriControls for blood gases, electrolytes, and chemistries
Store at 2 to 8 °C (35 to 46 °F). Controls may be stored at room temperature (18 to 30 °C, or 64 to 86 °F) for five days. Do not use after expiration date on the box and ampules.

i-STAT Controls for ACT and PT/INR
Store at 2 to 8 °C (35 to 46 °F). Do not use after expiration date on the box and vials. Controls should be used immediately after reconstitution.

i-STAT Controls for cTnI , BNP, CK-MB, and β-hCG
These controls require no reconstitution or frozen storage. They are stable until the expiration date on the vial label when stored unopened at 2 to 8 °C (35 to 46 °F). Once opened, the i-STAT cTnI, BNP, CK-MB, and β-hCG Controls are stable for 30 days when stored tightly capped at 2 to 8 °C.

Electronic Simulator
Store at room temperature and protect contact pads from contamination by replacing the plastic cap and placing the Electronic Simulator in its protective case after use.

BLOOD SPECIMENS

NOTE: blood collection devices, e.g., evacuated tubes, capillary tubes, and syringes, must be filled to the capacity of the device being used in order to ensure accurate test results.

Blood Collection Equipment

Cartridges for Blood Gas/Electrolytes/Chemistries/Hematocrit
- ❑ Skin puncture: lancet and capillary collection tube (lithium heparin, or balanced heparin for electrolytes and blood gases)
- ❑ Venipuncture: lithium heparin collection tubes and disposable transfer device.
- ❑ Arterial puncture: Plain syringe or blood gas syringe with heparin and labeled for the assays performed or with the least amount of heparin that will prevent clotting (10 U heparin/mL of blood)

Cartridges for ACT
- ❑ Skin puncture: not recommended
- ❑ Venipuncture and arterial puncture: plain plastic syringe without anticoagulant

Cartridges for PT/INR
- ❑ Skin puncture: lancet only needed. Cartridge can be filled directly from the finger.
- ❑ Venipuncture: plain plastic syringe without anticoagulant.

Cartridges for Troponin I/ cTnI and CK-MB
- ❑ Skin puncture: not recommended.
- ❑ Venipuncture: lithium or sodium heparin collection tubes and disposable transfer device (e.g., 1 cc syringe and a 16 to 20 gauge needle). Alternately, a plain syringe or plain collection tube and disposable transfer device can be used if the sample is tested within one minute of patient draw.

Cartridges for BNP
- ❑ Skin puncture: not recommended.
- ❑ Venipuncture: plastic EDTA collection tubes and disposable transfer device or plastic EDTA syringe.

Cartridges for Total β-hCG
- ❑ Skin puncture: not recommended.
- ❑ Venipuncture: plastic collection tubes or syringes with lithium or sodium heparin and a disposable transfer device, e.g., a 1 cc syringe and a 16 to 20 gauge needle.

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Blood Volume (See Table 1)

Table 1: Cartridge Panel Configurations and Blood Volume (Shading denotes calculated values)

Cartridge	Vol. (µL)	pH	PCO_2	PO_2	Na	K	Cl	iCa	Glu	BUN	Creat	Lact	Hct	TCO_2	ACT	PT/INR	CK-MB	cTnI	BNP	Total β-hCG	HCO_3	TCO_2	SO_2	BE	Anion Gap	Hb
CHEM8+	95				•	•	•	•	•	•	•		•	•											•	•
CG8+	95	•	•	•	•	•		•	•				•								•	•	•	•		•
EG7+	95	•	•	•	•	•		•					•								•	•	•	•		•
EG6+	95	•	•	•	•	•							•								•	•	•	•		•
CG4+	95	•	•	•								•									•	•	•	•		
G3+	95	•	•	•																	•	•	•	•		
EC8+	65	•	•		•	•	•		•	•			•								•	•		•	•	•
6+	65				•	•	•		•	•			•													•
EC4+	65				•	•			•				•													•
E3+	65				•	•							•													•
G	65								•																	
Crea	65										•															
ACT	40														•											
PT/INR	20															•										
cTnI	17																	•								
CK-MB	17																•									
BNP	17																		•							
Total β-hCG	17																			•						

Suitable Specimens

Suitable Specimens for Cartridges for Blood Gases, Electrolytes, Chemistries, and Hematocrit
- ❑ Fresh whole blood collected in capillary collection tube with balanced heparin.
- ❑ Fresh whole blood collected in a collection tube with lithium heparin anticoagulant. Fill collection tubes to capacity.
- ❑ Fresh whole blood collected in a plain plastic syringe or in a blood gas syringe labeled for the assays to be performed. Fill syringes for correct blood-to-heparin ratio.

Suitable Specimens for ACT
- ❑ Fresh whole blood without anticoagulant collected in a plastic syringe. If from an indwelling line, flush the line with 5mL saline and discard the first 5mL of blood or six dead space volumes of the catheter.
- ❑ Fresh whole blood collected in a plastic tube without anticoagulant, clot activators, or serum separators. Device used to transfer sample to cartridge must be plastic.

Suitable Specimens for PT/INR
- ❑ Fresh whole blood without anticoagulant collected in a plastic syringe or plastic evacuated tube without clot activators or serum separators. Device used to transfer sample to cartridge must be plastic.
- ❑ Fresh capillary whole blood dispensed directly into the cartridge from the finger.

Suitable Specimens for Troponin I/cTnI and CK-MB
- ❑ Fresh heparinized whole blood or plasma samples collected in syringes or evacuated tubes containing lithium or sodium heparin. Fill collection tube to capacity.
- ❑ Non heparinized whole blood samples tested within one minute of patient draw collected into a plastic syringe or plastic evacuated tube containing no additives.

Suitable Specimens for Total ß-hCG
- ❑ Fresh heparinized whole blood or plasma samples collected in plastic syringes or evacuated tubes containing lithium or sodium heparin. Fill collection tubes to capacity.

Suitable Specimens for BNP

❑ EDTA whole blood plasma samples collected in plastic syringes or evacuates tubes containing EDTA. Fill collection tubes to capacity.

Specimen Labeling

Unless the specimen is analyzed immediately after collection and then discarded, the specimen container must be labeled with the following information:

Patient name, sex, age
Patient ID number
Time and date of collection
Phlebotomist ID
Doctor's name

Specimen Collection and Handling

In-Dwelling Line

Back flush line with sufficient amount of blood to remove intravenous solution, heparin, or medications that may contaminate the sample. Recommendation: five to six times the volume of the catheter, connectors, and needle. If collecting sample for ACT, clear the line first with 5mL saline and discard the first 5mL of blood or six dead space volumes of the catheter.

Arterial Specimens

For cartridge testing of blood gases, electrolytes, chemistries, and hematocrit, fill a plain syringe or fill a blood gas syringe, labeled for the assays to be performed, to the recommended capacity, or use the least amount of liquid heparin anticoagulant that will prevent clotting. Under-filling syringes containing liquid heparin will decrease results due to dilution and will decrease ionized calcium results due to binding. For ionized calcium, balanced or low volume heparin blood gas syringes should be used. Do not expose sample to air or PCO$_2$ may decrease, pH may increase and PO$_2$ may decrease if the value is above or increase if the value is below the PO$_2$ of room air (approximately 150 mmHg).

For cartridge testing of ACT, use only a plain, plastic syringe without anticoagulant.

Mix blood and anticoagulant by rolling syringe between palms for at least 5 seconds each in two different directions, then invert the syringe repeatedly for at least 5 seconds. Discard the first two drops of blood. For blood gas testing, avoid or remove immediately any air drawn into syringe to maintain anaerobic conditions.

Test samples collected without anticoagulant immediately. Test samples for ACT and lactate immediately. For pH, blood gases, TCO$_2$ and ionized calcium, test within 10 minutes of collection. If not tested immediately, remix the sample and discard the first two drops of blood from a syringe before testing. Note that it may be difficult to property remix a sample in a 1.0 cc syringe. For other cartridge tests, test sample within 30 minutes of collection.

Venous Specimens

For cartridge testing of electrolytes, chemistries, and hematocrit, collect sample into an evacuated blood collection tube or a syringe containing sodium, lithium, or balanced heparin anticoagulant. For ionized calcium measurements, balanced heparin or 10 U of sodium or lithium heparin/mL of blood is recommended. Fill tubes to capacity; fill syringes for correct heparin-to-blood ratio. Incomplete filling causes higher heparin-to-blood ratio, which will decrease ionized calcium results and may affect other results. The use of partial-draw tubes (evacuated tubes that are adjusted to draw less than the tube volume, e.g., a 5 mL tube with enough vacuum to draw only 3 mL) is not recommended for blood gas or CHEM8+ cartridges because of the potential for decreased PCO2, HCO$_3$ and TCO$_2$ values.

For cartridge testing of Total β-hCG, use only heparinized whole blood or plasma samples collected in plastic syringes or evacuated tubes containing lithium or sodium heparin, filled to capacity.

For cartridge testing of ACT or PT/INR, use only a plain, plastic syringe or collection tube containing no anticoagulant. Use a plastic capillary tube, pipette, or syringe to transfer sample from a tube to a cartridge.

For glucose cartridge testing, EDTA is also an acceptable anticoagulant.

EDTA is the only acceptable anticoagulant for BNP Cartridge testing.

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Mix blood and anticoagulant by inverting a tube gently at least ten times. Roll a syringe vigorously between the palms for at least 5 seconds each in two different directions, then invert the syringe repeatedly for at least 5 seconds, then discard the first two drops of blood. Note that it may be difficult to properly mix a sample in a 1 cc syringe.

Test Sample collected without anticoagulant immediately. Test samples for ACT, lactate and PT/INR immediately. Test samples for pH, PCO2, TCO_2 and ionized calcium within 10 minutes of sample draw. If not tested immediately, remix the sample before testing and discard the first two drops of blood from a syringe before testing. For other cartridge tests, test sample within 30 minutes of collection.

Finger and Heelstick Specimens

For tests other than PT/INR, wipe away the first drop of blood, which contains excess tissue fluid which can increase the potassium result and decrease other test results. Avoid drawing air into the capillary tube. Use balanced heparin for ionized calcium. Test samples immediately to avoid clotting (especially in neonates). **Capillary samples are NOT recommended for ACT, Troponin I/cTnI, CK-MB, BNP and Total β-hCG.**

Criteria for Specimen Rejection

- ❑ Evidence of clotting
- ❑ Specimens collected in vacuum tubes with anticoagulant other than lithium or sodium heparin (or EDTA for BNP or glucose cartridges)
- ❑ Specimens for ACT or PT/INR collected in glass syringes or tubes or with anticoagulant of any kind
- ❑ Syringe for pH, PCO₂, PO₂ and TCO_2 with air bubbles in sample
- ❑ Incompletely filled vacuum tube for the measurement of ionized calcium, PCO₂, HCO_3 or TCO_2
- ❑ Other sample types such as urine, CSF, and pleural fluid

Precautions: avoid the following circumstances

- ❑ Drawing a specimen from an arm with an I.V.
- ❑ Stasis (tourniquet left on longer than one minute before venipuncture)
- ❑ Extra muscle activity (fist pumping)
- ❑ Hemolysis (alcohol left over puncture site, or a traumatic draw)
- ❑ Icing before filling cartridge
- ❑ Time delays before filling cartridge, especially lactate, ACT, and PT/INR
- ❑ Exposing the sample to air when measuring pH, PCO₂, PO₂ and TCO_2

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PROCEDURE FOR ANALYSIS

Preparation for Use

An individual cartridge may be used after standing 5 minutes, in its pouch, at room temperature. An entire box should stand at room temperature for one hour before cartridges are used.

Procedure for Cartridge Testing

- DO NOT insert cartridge to start test.
- DO NOT open cartridge pouch before scanning the barcode.
- If Quality Check Code 69 or 140 appears, see Analyzer Coded Messages Technical Bulletin for Troubleshooting Information.

1. Press ⏻ to turn on handheld.

2. Press ② for i-STAT.

3. Follow the handheld prompts.

4. Scan the lot number on the cartridge pouch.

   - Position barcode 3-9 inches from scanner window on handheld.
   - Press and hold SCAN to activate the scanner.
   - Align the red laser light so it covers the entire barcode.
   - The handheld will beep when it reads the barcode successfully.

   Note: If cartridge pouch does not have a barcode, enter the lot number manually using the numbered keys or press ENT to bypass the prompt. You may ignore any letters in the lot number.

5. Continue normal procedures for preparing the sample, filling, and sealing the cartridge.

6. Push the sealed cartridge into the handheld port until it clicks into place. Wait for the test to complete.

   Note: For ACT, PT/INR, Hct, and immunoassay testing, the handheld must remain on a level surface with the display facing up during testing. A level surface includes running the handheld in the downloader/recharger.

7. Review results.
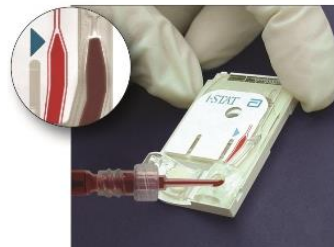
Alternative Procedure

Should the i-STAT System become inoperable for any reason, specimens should be collected and submitted to the laboratory in accordance with the Laboratory Procedure Manual.

RESULTS

Calculations

The i-STAT handheld contains a microprocessor that performs all calculations required for reporting results.

Displayed Results

Results are displayed numerically with their units. Electrolyte, chemistry and hematocrit results are also depicted as bar graphs with reference ranges marked under the graphs.

Suppressed Results

There are three conditions under which the i-STAT System will not display results:

1. Results outside the System's reportable ranges are flagged with a < or >, indicating that the result is below the lower limit or above the upper limit of the reportable range respectively. (See the table of Reportable Ranges.) The < > flag indicates that the results for this test were dependant on the result of a test flagged as either > or <.

     Action:
     Send specimen(s) to the laboratory for analysis, if necessary.

2. Cartridge results which are not reportable based on internal QC rejection criteria are flagged with *******.

     Action:
     Analyze the specimen again using a fresh sample and another cartridge. If the specimen integrity is not in question, the results that are not suppressed should be reported in the usual manner. If the result is suppressed again, send specimen(s) to the laboratory for analysis in accordance with the Laboratory Procedure Manual.

3. A Quality Check message will be reported instead of results if the handheld detects a problem with the sample, calibrant solution, sensors, or mechanical or electrical functions of the handheld during the test cycle.

     Action:
     Take the action displayed with the message that identifies the problem. Refer to the i-STAT or i-STAT 1 System Manual's Troubleshooting section or the "Analyzer Coded Messages" Technical Bulletin if necessary.

Printing and Transmitting Results

Printing Results from the i-STAT 1 Analyzer to the Martel Portable Printer or to the i-STAT Printer

<u>*Without Downloader or Downloader/Recharger*</u>

1. Turn printer on if green power light is not on.
2. Align IR windows of handheld and printer.
3. Display results.
4. Press the Print key.
5. Do not move handheld or printer until printing is complete.
6. If printer is not powered from a wall outlet, turn printer off.

<u>*With Downloader or Downloader/Recharger*</u>

1. Place handheld in Downloader or Downloader/Recharger that is wired to the printer.
2. Display results.
3. Press the Print key.
4. Do not move handheld or printer until printing is complete.

<u>Printing more than one result</u>

1. Turn the handheld on.
2. Press the Menu key.
3. Press 2 for Data Review.
4. Press 7 for List.
5. Scroll through the test records using the ← and → keys.
6. Press the numbered key for the test record(s). (Press the numbered key again to deselect a record.)
7. Align handheld and printer IR window or place in Downloader or Downloader/Recharger attached to printer.
    Press the Print key.
8. Do not move handheld or printer until printing is complete.
9. If printer is not powered from a wall unit using the AC adapter, turn printer off.

Transmitting Results from the i-STAT 1 Analyzer to the Data Manager

1. Place handheld in a Downloader or Downloader/Recharger.
2. Do not move handheld while the message "Communication in Progress" is displayed.

Reference Ranges,[1,2] Reportable Ranges, and Test Unit Conversions

Reference range means the range of test values expected from 95% of fasting individuals presumed to be healthy. Reportable range means the range of test values throughout which the measurement system's results have been shown to be valid. The following table contains the Reference Ranges (for adults) and Reportable Ranges applicable to the i-STAT System.

ANALYTE	UNIT	REFERENCE RANGE (arterial)	(venous)	REPORTABLE RANGE	UNIT CONVERSION
Sodium	mmol/L (mEq/L)	138 – 146	138 – 146	100 – 180	mmol/L x 1 = mEq/L <u>Example:</u> 140 mmol/L = 140 mEq/L
Potassium	mmol/L (mEq/L)	3.5 – 4.9	3.5 – 4.9	2.0 – 9.0	mmol/L x 1 = mEq/L
Chloride	mmol/L (mEq/L)	98 – 109	98 – 109	65 – 140	mmol/L x 1 = mEq/L
BUN	mg/dL	8 – 26	8 – 26	3 – 140	mg/dL BUN x 0.357 = mmol urea/L <u>Example:</u> 20 mg/dL BUN = 7.1 mmol urea/L
UREA	mmol/L	2.9 – 9.4	2.9 – 9.4	1 – 50	
Glucose	mg/dL	70 – 105	70 – 105	20 – 700	mg/dL x 0.055 = mmol/L <u>Example:</u> 100 mg/dL = 5.55 mmol/L g/L x 5.556 = mmol/L
	g/L	0.70 – 1.05	0.70 – 1.05	0.20 – 7.00	
	mmol/L	3.9 – 5.8	3.9 – 5.8	1.1 – 38.9	
Creatinine	mg/dL	0.6 – 1.3	0.6 – 1.3	0.2 – 20.0	mg/dL x 88.4 = μmol/L
	μmol/L	53 – 115	53 – 115	18 – 1768	
Ionized Calcium	mmol/L	1.12 – 1.32	1.12 – 1.32	0.25 – 2.50	mmol/L x 4 = mg/dL <u>Example:</u> 1.13 mmol/L x 4 = 4.52 mg/dL
	mg/dL	4.5 – 5.3	4.5 – 5.3	1.0 – 10.0	
pH		7.35 – 7.45	7.31 – 7.41	6.50 – 8.20	N/A
PCO_2	mmHg	35 – 45	41 – 51	5 – 130	mmHg x 0.133 = kPa <u>Example:</u> 35 mmHg x 0.133 = 4.66 kPa
	kPa	4.67 – 6.00	5.47 – 6.80	0.67 – 17.33	
PO_2	mmHg	80 – 105		5 – 800	mmHg x 0.133 = kPa <u>Example:</u> 83 mmHg x 0.133 = 11.04 kPa
	kPa	10.7 – 14.0		0.7 – 106.6	
TCO_2 (on the CHEM8+ cartridge only	mmol/L (mEq/L)	23 – 27	24 – 29	5 – 50	mmol/L x 1 = mEq/L

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ANALYTE	UNIT	REFERENCE RANGE		REPORTABLE RANGE	UNIT CONVERSION
		(arterial)	(venous)		
Hematocrit	% PCV	38 – 51	38 – 51	15 – 75	% PCV x 0.01 = Volume fraction <u>Example:</u> 40% PCV = 0.40 PCV
	Fraction	0.38 – 0.51	0.38 – 0.51	0.15 – 0.75	
Lactate	mmol/L	0.36 –1.25	0.90 – 1.70	0.30 – 20.00	mmol/L x 9.01 = mg/dL
	mg/dL	3.2 – 11.3	8.1–15.3	2.7 – 180.2	
HCO₃*	mmol/L (mEq/L)	22 – 26	23 - 28	1.0 – 85.0	mmol/L x 1 = mEq/L
TCO₂* (on all cartridges but CHEM8+)	mmol/L (mEq/L)	23 – 27	24 – 29	5 – 50	mmol/L x 1= mEq/L
BE*	mmol/L (mEq/L)	(-2) – (+3)	(-2) – (+3)	(-30) – (+30)	
Anion Gap*	mmol/L (mEq/L)	10 – 20	10 – 20	(-10) – (+99)	
sO₂*	%	95 – 98		0 - 100	% x 0.01 = fraction saturated
Hb*	g/dL	12 – 17	12 – 17	5.1 – 25.5	g/dL x 10 = g/L
	g/L	120 – 170	120 – 170	51 – 255	
	mmol/L	7 – 11	7 – 11	3.2 – 15.8	
Celite ACT	sec	74 – 125 (PREWARM) 84 – 139 (NONWARM)	74 – 125 (PREWARM) 84 – 139 (NONWARM)	50 – 1000	
Kaolin ACT	sec	74 – 137 (PREWARM) 82 – 152 (NONWARM)	74 – 137 (PREWARM) 82 – 152 (NONWARM)	50 – 1000	
Prothrombin Time/PT	INR			0.9 – 8.0#	
Troponin I/cTnI	ng/mL (µg/L)		0.00 – 0.03** 0.00 – 0.08***	0.00 – 50.00##	ng/mL x 1 = µg/L
Creatine Kinase MB/CK-MB	ng/mL (µg/L)		0.0 – 3-5****	0.0 – 150.0	ng/mL x 1 = µg/L
B-Type Natriuretic Peptide/BNP	pg/mL (ng/L)		<15-50****	15 – 5000	pg/mL x 1 = ng/L
Total β-hCG	IU/L		<5.0	5.0 – 2000.0	

*Calculated values.

#Performance characteristics have not been established for INRs above 6.0.

**Represents the 0–97.5% range of results. Each facility should establish its own reference range using the i-STAT cTnI assay.

##Performance characteristics have not been established for cTnI values above 35.00 ng/mL.

***Represents the 0–99% range of results. Each facility should establish its own reference range using the i-STAT cTnI assay.

****Represents the 0–95% range of results. Each facility should establish its own reference range using the i-STAT assay

Critical Results [3]

Critical results are test results that fall outside high and low critical limits that define the boundaries of life-threatening values for a test. Critical results represent an emergency condition and must be reported immediately to the patient's attending physician or nurse.

ANALYTE (units)	ADULT		CHILDREN		NEONATES	
	low	high	low	high	low	high
Sodium (mmol/L)	120	158	121	156	121	156
Potassium (mmol/L)	2.8	6.2	2.8	6.4	2.8	6.5
Chloride (mmol/L)	75	126	77	121	77	121
TCO_2 (mmol/L)	11	40	11	39	–	–
Ionized Calcium (mmol/L)	0.78	1.58	0.74	1.57	–	–
pH	7.21	7.59	7.21	7.59	–	–
PCO_2 (mmHg)	19	67	21	66	–	–
PO_2 (mmHg)	43	–	45	124	37	92
BUN (mg/dL)	–	104	–	55	–	55
Glucose (mg/dL)	46	484	46	445	32	328
Creatinine	–	7.4	–	3.8	–	–
Lactate						
Hematocrit (% PCV)	18	61	20	62	33	71
Celite ACT						
Kaolin ACT						
PT/INR						
Troponin I/cTnI						
Creatine Kinase MB/ CK-MB						
B-Type Natriuretic Peptide/ BNP						
Total β-hCG						

Interferences

An interferent is a substance which, if present at significant levels in the blood specimen being analyzed, will produce an error in the result of the analyte being measured.

ANALYTE	INTERFERENT	INTERFERENT CONCENTRATION	EFFECT ON ANALYTE RESULT
Sodium	Bromide	37.5 mmol/L	Use Another Method.
	Nithiodote (sodium thiosulfate)	16.7 mmol/L	Increase ($\uparrow$) Na
Potassium	Bromide	37.5 mmol/L	Use Another Method.
	Nithiodote (sodium thiosulfate)	16.7 mmol/L	Decrease ($\downarrow$) K
Chloride	Acetylcysteine	10.2 mmol/L	Increase ($\uparrow$) Cl
	Bromide	37.5 mmol/L	Use Another Method.
	Bromide (therapeutic)	2.5 mmol/L	Increase ($\uparrow$) Cl
	Salicylate	4.34 mmol/L	Increase ($\uparrow$) Cl
	Thiocyanate	6.9 mmol/L	Increase ($\uparrow$) Cl
	Nithiodote (sodium thiosulfate)	16.7 mmol/L	Increase ($\uparrow$) Cl
Ionized Calcium	Acetaminophen	1.32 mmol/L	Decrease ($\downarrow$) iCa
	Magnesium	1.0 mmol/L	Increase ($\uparrow$) iCa by up to 0.04 mmol/L
	Acetylcysteine	10.2 mmol/L	Decrease ($\downarrow$) iCa
	Bromide	37.5 mmol/L	Use Another Method.
	Lactate	6.6 mmol/L	Decrease ($\downarrow$) iCa by up to 0.07 mmol/L
	Salicylate (therapeutic)	0.5 mmol/L	Decrease ($\downarrow$) iCa by up to 0.03 mmol/L
	Salicylate	4.34 mmol/L	Decrease ($\downarrow$) iCa
	Nithiodote (sodium thiosulfate)	16.7 mmol/L	Decrease ($\downarrow$) iCa
	Thiocyanate	6.9 mmol/L	Decrease ($\downarrow$) iCa Use Another Method.
Glucose	Acetaminophen	1.32 mmol/L	Increase ($\uparrow$) glucose
	Acetylcysteine	10.2 mmol/L	Decrease ($\downarrow$) glucose
	Bromide	37.5 mmol/L	Use Another Method.
	Bromide (therapeutic)	2.5 mmol/L	Decrease ($\downarrow$) glucose
	pH	pH: per 0.1 pH units below 7.4 @ 37°C	Decrease ($\downarrow$) glucose by 0.9 mg/dL (0.05 mmol/L)
		pH: per 0.1 pH units above 7.4 @ 37°C	Increase ($\uparrow$) glucose by 0.8 mg/dL (0.04 mmol/L)

ANALYTE	INTERFERENT	INTERFERENT CONCENTRATION	EFFECT ON ANALYTE RESULT
Glucose (cont.)	Oxygen	PO_2 less than 20 mmHg @ 37°C	May decrease (↓) glucose
	Hydroxyurea	0.92 mmol/L	Increase (↑) glucose Use Another Method.
	Nithiodote (sodium thiosulfate)	16.7 mmol/L	Decrease (↓) glucose
	Thiocyanate	6.9 mmol/L	Decrease (↓) glucose
Lactate	Bromide	37.5 mmol/L	Use Another Method.
	Hydroxyurea	0.92 mmol/L	Increase (↑) lactate Use Another Method.
	Glycolic Acid	10.0 mmol/L	Increase (↑) lactate Use Another Method.
BUN/Urea	Bromide	37.5 mmol/L	Use Another Method.
	Hydroxyurea	0.92 mmol/L	Increase (↑) BUN/Urea results
	Nithiodote (sodium thiosulfate)	16.7 mmol/L	Decrease (↓) BUN/Urea results
Creatinine	Acetaminophen	1.32 mmol/L	Increase (↑) creatinine
	Ascorbate	0.34 mmol/L	Increase (↑) creatinine by up to 0.3 mg/dL
	Bromide (therapeutic)	2.5 mmol/L	Increase (↑) creatinine
<2 mg/dL	PCO_2	Above 40 mmHg	Increase (↑) creatinine by 6.9% per 10 mmHg PCO_2
		Below 40 mmHg	Decrease (↓) creatinine by 6.9% per 10 mmHg PCO_2
>2 mg/dL	PCO_2	Above 40 mmHg	Decrease (↓) creatinine by 3.7% per 10 mmHg PCO_2
		Below 40 mmHg	Increase (↑) creatinine by 3.7% per 10 mmHg PCO_2
	Hydroxyurea	0.92 mmol/L	Increase (↑) Creatinine Use Another Method.
	Acetylcysteine	10.2 mmol/L	Increase (↑) creatinine
	Creatine	0.382 mmol/L	Increase (↑) creatinine by up to 0.3 mg/dL
	Glycolic Acid	10.0 mmol/L	Decrease (↓) creatinine Use Another Method.
	Nithiodote (sodium thiosulfate)	16.7 mmol/L	Increase (↑) creatinine

ANALYTE	INTERFERENT	INTERFERENT CONCENTRATION	EFFECT ON ANALYTE RESULT
Hematocrit	White Blood Count (WBC)	Greater than 50,000 WBC/µL	May Increase ($\uparrow$) hematocrit
	Total Protein	For measured Hct<40% For each g/dL below 6.5 For each g/dL above 8.0	Decrease ($\downarrow$) Hct by 1% PCV Increase ($\uparrow$) Hct by 1% PCV
		For measured Hct≥40% For each g/dL below 6.5 For each g/dL above 8.0	Decrease ($\downarrow$) Hct by 0.75% PCV Increase ($\uparrow$) Hct by 0.75% PCV
	Lipids	Abnormally high	Increase ($\uparrow$) Hct
	Bromide	37.5 mmol/L	Increased rate of star (***) outs
Celite ACT	Aprotinin		Falsely extends Celite ACT times
PCO$_2$	Propofol (Diprovan®) Thiopental Sodium		For patients administered propofol or thiopental sodium, APOC recommends the use of G3+, CG4+, CG8+, EG6+, and EG7+ cartridges, which are free from clinically significant interference at all relevant therapeutic doses. APOC does not recommend the use of EC8+ cartridges for patients receiving propofol or thiopental sodium.
PT/INR	Cubicin® (daptomycin for injection) Chlorhexidine Gluconate		Falsely extends prothrombin time (PT) and INR May falsely extend prothrombin time (PT) and INR

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QUALITY CONTROL

Daily Procedures

Handheld Verification

Verify the performance of each handheld in the i-STAT System using the internal or external Electronic Simulator every 24 hours of use, or as needed for regulatory compliance. In the USA, verification is required every 8 hours for blood gases, hematocrit, ACT, and PT/INR.

    Action:

    If PASS is displayed on the handheld screen (after using the external Electronic Simulator):

- ❑ Remove the external Electronic Simulator after the LCK or Simulator Locked message disappears from the display screen.
- ❑ Transmit the result to the Central Data Station.
- ❑ Use the handheld as required.

    Note: If the internal Electronic Simulator is used, the "PASS" message will not be displayed on the handheld screen. The "PASS" record will appear in the handheld's stored results for transmission to the Central Data Station.

    Remedial Action:

    If FAIL is displayed on the analyzer screen:

- ❑ Repeat the procedure with the same external Electronic Simulator or rerun the cartridge if the internal Electronic Simulator is being used. If PASS is displayed use the handheld as required.
- ❑ If FAIL is displayed repeat the procedure with a different external Electronic Simulator.

    If PASS is displayed with the second external Electronic Simulator:

- ❑ Use the handheld as required.
- ❑ Deliver the questionable external Electronic Simulator to the i-STAT System Coordinator.

    If FAIL is displayed with the second external Electronic Simulator:

- ❑ DO NOT analyze patient samples with the handheld.
- ❑ Transmit the results to the Central Data Station.
- ❑ Deliver the faulty handheld to the i-STAT System Coordinator.
- ❑ Record the failure in the i-STAT QC Log along with the action taken.

Verification of Cartridge Storage Conditions

    Refrigerated Cartridges

- ❑ Verify that the cartridges stored in the refrigerator are all within the expiration date printed on the boxes.
  Deliver any expired cartridges to the i-STAT System Coordinator.
- ❑ Verify that the refrigerator did not exceed the limits of 2 to 8 °C (35 to 46 °F).
- ❑ Document in the i-STAT QC Log.

    Action:

    If the temperature of the cartridge storage refrigerator is within the range of 2 to 8 °C (35 to 46 °F) use cartridges as required.

    Remedial Action:

    If the temperature is outside the range of 2 to 8 °C (35 to 46 °F), notify the i-STAT System Coordinator immediately. Record the QC failure in the i-STAT QC Log along with the actions taken as described in Section 14 (Quality Control) of the i-STAT 1 System Manual.

Room Temperature Cartridges

❑ Verify that all boxes of cartridges at room temperature have been out of the refrigerator less than the time frame indicated on the cartridge box. Deliver any expired cartridges to the i-STAT System Coordinator.

❑ Verify that room temperature has not exceeded 30 °C (86 °F).

❑ Document in the i-STAT QC log.

Action:

If the measured temperature of the room has been continuously below 30 °C (86 °F) use cartridges as required.

Remedial Action:

If the measured room temperature has exceeded 30 °C (86 °F) for any period of time:

❑ Quarantine the cartridges.

❑ Notify the i-STAT System Coordinator immediately.

❑ DO NOT USE the cartridges.

❑ Record the out-of-control event in the i-STAT QC Log and the action taken.

Monthly Procedures

Print Electronic Simulator Results

Print a copy of the Electronic Simulator results from the Central Data Station. Include the report in the i-STAT QC Log.

❑ CDS version 5 and above: Click on the Simulator Viewer.

Print Control Fluid Analysis Results

Print results for any control fluids analyzed from the Central Data Station. Include the report in the i-STAT QC Log.

❑ CDS version 5 and above: Click on the Control Results Viewer.

Periodic Procedures for Cartridges

For acceptance of newly received cartridge lots, check the Temperature Monitor and perform integrity testing.

Note: This is not a manufacturer's system instruction. It is a suggestion to comply with regulatory requirements that may pertain to your laboratory.

Check Temperature Monitor

i-STAT cartridges are shipped refrigerated with a four-window indicator to monitor temperature during transit.

Note: All control and calibration verification materials, except for those shipped on dry ice, will also include a four-window indicator to monitor temperature during transit.

Action:

❑ Fill out the record of receipt and forward materials to refrigerator.

❑ If all windows are white or if only the A or B windows are blue or the 1 or 2 windows are red, then transit temperatures were satisfactory and the cartridges can be used.

Remedial Action:

If the C or D windows are blue, or the 3 or 4 windows are red:

❑ Quarantine the suspect cartons.

❑ Notify the i-STAT System Coordinator immediately.

❑ DO NOT USE cartridges from the suspect cartons.

❑ Record the out-of-control event in the i-STAT QC Log.

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Integrity Testing*

Verify the integrity of cartridges included in every shipment, upon receipt, by analyzing two levels of appropriate controls (see table below) along with a representative sample of each new lot and by comparing the results to the expected values published in the Value Assignment Sheets. Any analyzer that has passed the Electronic Simulator test may be used in the verification.

*Note: the information in the above paragraph is not a manufacturer's system instruction. It is a suggestion to comply with regulatory requirements that may pertain to your laboratory.

Verification of Cartridges Using 2 Levels of Specified Controls	
CARTRIDGE TYPE	**CONTROL TYPE**
G, Crea, G3+, CG4+	TriControls[1] *or* i-STAT controls[1]
CHEM8+, E3+, EC4+, 6+, EC8+, EG6+, EG7+, CG8+	TriControls[1]
ACTk, ACTc	i-STAT ACT controls[2]
PT/INR	i-STAT PT/INR controls[2]
cTnI	i-STAT cTnI controls[1]
CK-MB	i-STAT CK-MB controls[1]
BNP	i-STAT BNP controls[1]
Total β-hCG	i-STAT Total β-hCG controls[1]

[1] Use Level 1 and 3 Controls.
[2] Use Level 1 and 2 Controls.

Procedure for testing cartridges with i-STAT Level 1 and Level 3 Controls:

1. Prior to testing cartridges that measure PO2, ampules should stand at room temperature a minimum of 4 hours before use. When testing other cartridges (G, Crea, E3+, EC4+, 6+, CHEM8+, or EC8+), ampules may be used once the fluid has reached room temperature, approximately 30 minutes for individual ampules. For best results, ampules, cartridges, and handhelds should be at the same temperature. When using cartridges that contain sensors for measuring ionized calcium, pH, PCO$_2$, or PO$_2$ (G3+, EG6+, EG7+, CG4+, CG8+, CHEM8+, or EC8+), a separate ampule must be used for each cartridge being tested; if these sensors are not present (i.e., the 6+ cartridge), the contents of one ampule may be used to fill more than one cartridge as long as the cartridges are filled and inserted into a handheld within 10 minutes of opening the ampule.

2. Immediately before use, shake the ampule vigorously for 5 to 10 seconds to equilibrate the liquid and gas phases. To shake, hold the ampule at the tip and bottom with forefinger and thumb to minimize increasing the temperature of the solution. If necessary, tap the tip of the ampule to send solution back into the bottom section of the ampule. Protect fingers with gauze, tissue, or glove, or use an ampule breaker to snap off the tip of the ampule at the neck.

3. Immediately transfer the solution from the ampule into a plain capillary tube or plain syringe, and then immediately transfer the solution into a cartridge. Immediately seal the cartridge and insert it into a handheld. It is important not to expose the solution to room air since this will alter the results.

   ❑ When using a capillary tube, fill from the bottom of the ampule. Avoid drawing solution from the surface by covering the far end of the tube as it is inserted into the ampule. Once the open end of the tube rests at the bottom of the ampule, uncover the other end to allow filling by capillary action.

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❑ When using a syringe (1 cc or 3 cc syringes with 16 to 20 gauge needles are recommended), slowly draw approximately 1 cc of solution from the bottom of the ampule. If air is trapped between the leading edge of the solution and the plunger, do not invert the syringe to expel it; this will not affect solution near the tip of the syringe. If air bubbles are continually drawn into the syringe, or if a bubble is trapped near the tip of the syringe, discard the ampule and syringe and use a fresh ampule and syringe. Expel one or two drops from the syringe before filling the cartridge.

❑ Do not use solution left in the syringe, ampule, or capillary tube for additional testing of the cartridges that contain sensors for ionized calcium, pH, PCO$_2$, or PO$_2$. However, cartridges without these sensors may be tested with remaining fluids if within 10 minutes of opening the ampule.

4. Compare results to the value assignment sheet ranges. Check that the lot number on the control ampule matches the lot number on the package insert and that the software version listed on the insert matches the software installed in the handheld. If all results are within expected ranges, use the cartridges as needed. If available, transmit the results to the Data Manager.

Procedure for testing cartridges with TriControls Level 1 and Level 3 Controls:

1. Prior to testing cartridges that measure PO2, ampules should stand at room temperature a minimum of 4 hours before use. When testing other cartridges (G, Crea, E3+, EC4+, 6+, EC8+, or CHEM8+), ampules may be used once the fluid has reached room temperature, approximately 30 minutes for individual ampules. For best results, ampules, cartridges, and handhelds should be at the same temperature. When using cartridges that contain sensors for measuring ionized calcium, pH, PCO$_2$, or PO$_2$ (G3+, EG6+, EG7+, CG4+, CG8+, EC8+, or CHEM8+), a separate ampule must be used for each cartridge being tested; if these sensors are not present (i.e., the 6+ cartridge), the contents of one ampule may be used to fill more than one cartridge as long as the cartridges are filled and inserted into a handheld within 10 minutes of opening the ampule.

2. Immediately before use, shake the ampule vigorously for 5 to 10 seconds to equilibrate the liquid and gas phases. To shake, hold the ampule at the tip and bottom with forefinger and thumb to minimize increasing the temperature of the solution. If necessary, tap the tip of the ampule to send solution back into the bottom section of the ampule. Protect fingers with gauze, tissue, or glove, or use an ampule breaker to snap off the tip of the ampule at the neck.

3. Immediately transfer the solution from the ampule into a plain capillary tube or plain syringe, and then immediately transfer the solution into a cartridge. Immediately seal the cartridge and insert it into a handheld. It is important not to expose the solution to room air since this will alter the results.

❑ When using a capillary tube, fill from the bottom of the ampule. Avoid drawing solution from the surface by placing a finger over the far end of the tube as it is inserted into the ampule. Once the open end of the tube rests at the bottom of the ampule, uncover the other end to allow filling by capillary action.

❑ When using a syringe (1 cc or 3 cc syringes with 16 to 20 gauge needles are recommended), slowly draw approximately 1 cc of solution from the bottom of the ampule. If air is trapped between the leading edge of the solution and the plunger, do not invert the syringe to expel it; this will not affect solution near the tip of the syringe. If air bubbles are continually drawn into the syringe, or if a bubble is trapped near the tip of the syringe, discard the ampule and syringe and use a fresh ampule and syringe. Expel one or two drops from the syringe before filling the cartridge.

❑ Do not use solution left in the syringe, ampule, or capillary tube for additional testing of the cartridges that contain sensors for ionized calcium, pH, PCO$_2$, or PO$_2$. However, cartridges without these sensors may be tested with remaining fluids if within 10 minutes of opening the ampule.

4. Compare results to the Value Assignment Sheet ranges. Ensure that the lot number printed on the Value Assignment Sheet matches the lot number on the label of the ampule and that the software version above the target value table matches the software version in the handheld. If all results are within expected ranges, use the cartridges as needed. If available, transmit the results to the Data Manager.

Remedial Action:

If any results are outside the published expected ranges:

- ❑ DO NOT USE cartridges from the suspect lot.
- ❑ Quarantine the suspect lot.
- ❑ Notify the i-STAT System Coordinator immediately.
- ❑ Record the QC failure in the i-STAT QC Action Log along with the action taken.

Procedure for testing cartridges with i-STAT Level 1 and Level 2 ACT or PT/INR Controls

1. Prior to use, allow one vial each of the lyophilized plasma and calcium chloride reconstituting fluid to stand at room temperature for a minimum of 45 minutes.
2. Remove the cap and stopper from the vials and pour the entire contents of the calcium chloride vial into the lyophilized plasma vial. Place the stopper back on the reconstituted vial.
3. Allow the vial to sit for 1 minute and then mix the contents by swirling gently for 1 minute, then inverting slowly for 30 seconds.
4. Use a plastic pipette, syringe, or capillary tube without anticoagulant to transfer the solution to an ACT cartridge.
5. Immediately seal the cartridge and insert it into a handheld. This process must be completed within 30 seconds of the complete reconstitution of the control sample.
6. Compare results to the value assignment sheet ranges. If results are within the expected ranges, use the cartridges as needed. If available, transmit results to the Data Manager.

Remedial Action:

If any results are outside the published expected ranges:

- ❑ DO NOT USE cartridges from the suspect lot.
- ❑ Quarantine the suspect lot.
- ❑ Notify the i-STAT System Coordinator immediately.
- ❑ Record the QC failure in the i-STAT QC Action Log along with the action taken.

Procedures for testing cartridges with i-STAT cTnI, BNP, and CK-MB controls

1. i-STAT cTnI, BNP, and CK-MB Controls are ready-to-use liquid control requiring no reconstitution or frozen storage. They are stable until the expiration date on the vial label when stored unopened at $2-8$ °C (35 to 46 °F). Once opened, the i-STAT cTnI, BNP, and CK-MB Controls are stable for 30 days when stored tightly capped at $2-8$ °C.
2. Access the Control option under Quality Tests in the Administration Menu. Enter the required information. The handheld allows 15 minutes (or the customized timeout period) to insert the cartridge after the last data entry.
3. Immediately before use, gently mix the contents of the control vial to ensure homogeneity. Avoid foaming of the sample.
4. Open the vial and transfer a drop of the solution into the i-STAT cartridge using a plain capillary tube, plain syringe, or plastic transfer pipette. Tightly recap the control vial and store it at $2-8$ °C (35 to 46 °F).
5. Seal the cartridge and immediately insert it into the i-STAT 1 Analyzer.
6. Compare the result to the Value Assignment Sheet value. Always ensure that the lot number and software revision on the Value Assignment Sheet matches the lot number of the vial in use and the software revision in the handheld. Should results fall outside the range, refer to the Troubleshooting section of i-STAT 1 System Manual section 14 (Quality Control).
7. If available, transmit results to the Data Manager.

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Remedial Action:

If any results are outside the published expected ranges:

- ❑ DO NOT USE cartridges from the suspect lot.
- ❑ Quarantine the suspect lot.
- ❑ Notify the i-STAT System Coordinator immediately.
- ❑ Record the QC failure in the i-STAT QC Action Log along with the action taken.

Procedures for testing cartridges with i-STAT Total β-hCG controls

1. i-STAT β-hCG Controls are ready-to-use liquid control requiring no reconstitution or frozen storage. They are stable until the expiration date on the vial label when stored unopened at 2-8 °C. Once opened, the i-STAT β-hCG Controls are stable for 30 days when stored tightly capped at 2-8 °C.

2. Access the Control option under Quality Tests in the Administration Menu. Enter the required information. The handheld allows 15 minutes (or the customized timeout period) to insert the cartridge after the last data entry.

3. Immediately before use, gently mix the contents of the control vial to ensure homogeneity. Avoid foaming of the sample.

4. Open the vial and transfer a drop of fluid into the i-STAT Total β-hCG cartridge using the vial dropper tip. Tightly recap the control vial and store it at 2-8 °C.

5. Seal the cartridge and immediately insert it into the i-STAT 1 Analyzer.

6. Compare the result to the Value Assignment Sheet value. Always ensure that the lot number and software revision on the Value Assignment Sheet matches the lot number of the vial in use and the software revision in the handheld. Should results fall outside the range, refer to the Troubleshooting section of i-STAT 1 System Manual section 14 (Quality Control).

7. If available, transmit results to the Data Manager.

Remedial Action:

If any results are outside the published expected ranges:

- ❑ DO NOT USE cartridges from the suspect lot.
- ❑ Quarantine the suspect lot.
- ❑ Notify the i-STAT System Coordinator immediately.
- ❑ Record the QC failure in the i-STAT QC Action Log along with the action taken.

CALIBRATION

For cartridges, calibration is automatically performed as part of the test cycle on each cartridge type, except coagulation and immunoassay cartridges. Operator intervention is not necessary.

CLINICAL SIGNIFICANCE

Analyte	Some Causes of Increased Values	Some Causes of Decreased Values
Sodium	Dehydration Diabetes insipidus Salt poisoning Skin losses Hyperaldosteronism CNS disorders	Dilutional hyponatremia (cirrhosis) Depletional hyponatremia Syndrome of inappropriate ADH
Potassium	Renal glomerular disease Adrenocortical insufficiency Diabetic Ketoacidosis (DKA) Sepsis *In vitro* hemolysis	Renal tubular disease Hyperaldosteronism Treatment of DKA Hyper-insulinism Metabolic alkalosis Diuretic therapy
Chloride	Prolonged diarrhea Renal tubular disease Hyperparathyroidism Dehydration	Prolonged vomiting Burns Salt-losing renal disease Over-hydration Thiazide therapy
Ionized Calcium	Dehydration Hyperparathyroidism Malignancies Immobilization Thiazide diuretics Vitamin D intoxication	Hypoparathyroidism Early neonatal hypocalcemia Chronic renal disease Pancreatitis Massive blood transfusions Severe malnutrition
BUN	Impaired renal function Prerenal azotemia (e.g., shock) Postrenal azotemia GI bleeding High protein diet	Pregnancy Severe liver insufficiency Over-hydration Malnutrition

Analyte	Some Causes of Increased Values	Some Causes of Decreased Values
Glucose	Diabetes mellitus Pancreatitis Endocrine disorders (e.g., Cushing's syndrome) Drugs (e.g., steroids, thyrotoxicosis) Chronic renal failure Stress I.V. glucose infusion	Insulinoma Adrenocortical insufficiency Hypopituitarism/Massive liver disease Ethanol ingestion/Reactive hypoglycemia Glycogen storage disease
Creatinine	Impaired renal function	
Lactate	Hypoxia (shock, hypovolumia, left ventricular failure) diabetes mellitus neoplasia liver disease drug or toxins (ethanol, methanol, salicylates) glycolic acid as a product of ethylene glycol metabolism	
pH	Respiratory alkalosis Metabolic alkalosis	Respiratory acidosis Metabolic acidosis
PCO_2	Acute Respiratory Acidosis: • *Depression of respiratory center* • *Suppressed neuromuscular system* • *Pulmonary disorders* • *Inadequate mechanical ventilation* Chronic respiratory acidosis • *Decreased alveolar ventilation* • *Hypoventilation* Compensation in metabolic alkalosis	Respiratory alkalosis: • *Increased stimulation of respirator center* • *Hypermetabolic states* • *Mechanical hyperventilation* Compensation in metabolic acidosis
PO_2	Breathing oxygen-enriched air	Carbon-monoxide exposure Pulmonary disorders Myocardial infarction Congestive heart failure
HCO_3 *and* **TCO_2**	Primary metabolic alkalosis Primary respiratory acidosis	Primary metabolic acidosis Primary respiratory alkalosis

Analyte	Some Causes of Increased Values	Some Causes of Decreased Values
Hematocrit	Dehydration Burns Impaired ventilation Renal disorders	Hemolytic anemias Iron deficiency Marrow depression Blood loss
ACT Celite	Administration of heparin for medical or surgical procedures. Administration of aprotinin.	
PT/INR	Administration of oral anticoagulant therapy.	
ACT Kaolin	Administration of heparin for medical or surgical procedures.	
cTnI	Myocardial Infarction Coronary vasospasm Cardiac contusion/trauma Rhythm disturbance (SVT, AF) Chemotherapy (e.g., Adriamycin) Myocarditis/pericarditis Infiltrative diseases (e.g., Amyloidosis, sarcoidosis, hemochromatosis, connective tissue disease) Congestive heart failure Heart transplantation Cardiac procedures (PTCA, DC cardioversion) Intracranial hemorrhage/stroke Pulmonary embolism Pulmonary hypertension Chronic renal insufficiency Sepsis Strenuous exercise Certain drug ingestions	Rare antibodies to troponin or its circulating complexes

Analyte	Some Causes of Increased Values	Some Causes of Decreased Values
CK-MB	Myocardial Infarction Coronary vasospasm Cardiac contusion/trauma Myocarditis/pericarditis Infiltrative diseases (e.g., Amyloidosis, sarcoidosis, hemochromatosis, connective tissue disease) Cardiac procedures (PTCA, DC cardioversion) Intracranial hemorrhage/stroke Pulmonary embolism Pulmonary hypertension Chronic renal insufficiency Sepsis Strenuous exercise Certain drug ingestions (cocaine) Skeletal muscle disease	Lean muscle mass
BNP	Congestive heart failure Chronic obstructive pulmonary disease (COPD) Asthma Pulmonary hypertension Cor pulmonale Pulmonary embolism Acute coronary syndrome Chronic renal failure Age Female sex	Obesity (BMI >30 Kg/m^2) Flash pulmonary edema (elevation may be delayed)
Total β-hCG	Pregnancy Gestational trophoblastic disease Nontrophoblastic neoplasms Menopause	

PRINCIPLES OF MEASUREMENT

Sodium, Potassium, Chloride, Ionized Calcium, pH, and $P\text{CO}_2$

are measured by ion-selective electrode potentiometry. Concentrations are calculated from the measured potential through the Nernst equation.

Urea

is first hydrolyzed to ammonium ions in a reaction catalyzed by the enzyme urease. The ammonium ions are measured by an ion-selective electrode and the concentration is calculated from the measured potential through the Nernst equation.

Glucose

is measured amperometrically. Oxidation of glucose, catalyzed by the enzyme glucose oxidase, produces hydrogen peroxide. The liberated hydrogen peroxide is oxidized at an electrode to produce an electric current which is proportional to the glucose concentration.

Creatinine

is hydrolyzed to creatine in a reaction catalyzed by the enzyme creatinine amidohydrolase. Creatine is then hydrolyzed to sarcosine in a reaction catalyzed by the enzyme creatine amidinohydrolase. The oxidation of sarcosine, catalyzed by the enzyme sarcosine oxidase, produces hydrogen peroxide. The liberated hydrogen peroxide is oxidized at the platinum electrode to produce a current which is proportional to the creatinine concentration.

Lactate

is measured amperometrically. The enzyme lactate oxidase, immobilized in the lactate biosensor, selectively converts lactate to pyruvate and hydrogen peroxide. The liberated hydrogen peroxide is oxidized at the platinum electrode to produce a current which is proportional to the lactate concentration.

$P\text{O}_2$

is measured amperometrically. The oxygen sensor is similar to a conventional Clark electrode. Oxygen permeates through a gas permeable membrane from the blood sample into an internal electrolyte solution where it is reduced at the cathode. The oxygen reduction current is proportional to the dissolved oxygen concentration.

Hematocrit

is determined conductometrically. The measured conductivity, after correction for electrolyte concentration, is inversely related to the hematocrit.

ACT

is determined amperometrically. The conversion of a thrombin substrate is initiated by mixing a whole blood sample (without anticoagulant) with a particulate clotting activator – either Celite® brand diatomaceous earth or kaolin. The substrate used in the electrogenic assay has an amide linkage that mimics the thrombin-cleaved amide linkage in fibrinogen. The product of the thrombin-substrate reaction is the electroactive compound that is detected amperometrically. The time of detection is measured in seconds and the result is reported as a whole blood time (WBT).

PT/INR

is determined amperometrically. The conversion of a thrombin substrate is initiated by mixing a whole blood sample (without anticoagulant) with tissue thromboplastin. The substrate used in the electrogenic assay has as amide linkage that mimics the thrombin–cleaved amide linkage in fibrinogen. The product of the thrombin–substrate reaction is the electroactive compound that is detected amperometrically. The time of detection is measured in seconds and reported as INR and/or seconds.

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Troponin I/cTnI

is determined amperometrically using a two-site ELISA method. Antibodies specific for human cardiac troponin I (cTnI) are located on an electrochemical sensor fabricated on a silicon chip. Also deposited in another location on the sensor silicon chip is an antibody/alkaline phosphatase enzyme conjugate specific to a separate portion of the cTnI molecule. The whole blood or plasma sample is brought into contact with the sensors allowing the enzyme conjugate to dissolve into the sample. The cTnI within the sample becomes labeled with alkaline phosphatase and is captured onto the surface of the electrochemical sensor during an incubation period of approximately seven minutes. The sample, as well as excess enzyme conjugate, is washed off the sensors. Within the wash fluid is a substrate for the alkaline phosphatase enzyme. The enzyme bound to the antibody/antigen/antibody sandwich cleaves the substrate releasing an electrochemically detectable product. The electrochemical (amperometric) sensor measures this enzyme product which is proportional to the concentration of cTnI within the sample.

Creatine Kinase MB/CK-MB

is determined amperometrically using a two-site ELISA method. Antibodies specific for an epitope unique to the CK-MB subunit, that therefore do not bind CK-MM or CK-BB, are located on an electrochemical sensor fabricated on a silicon chip. Also deposited in another location on the sensor silicon chip is an antibody/alkaline phosphatase enzyme conjugate specific to an epitope on the B subunit of creatine kinase. The specificity of the conjugate antibody to the B subunit allows this conjugate to recognize CK-MB and CK-BB, but not CK-MM. The whole blood or plasma sample is brought into contact with the sensors allowing the enzyme conjugate to dissolve into the sample. The CK-MB within the sample becomes labeled with alkaline phosphatase and is captured onto the surface of the electrochemical sensor during an incubation period of approximately three minutes. The sample is washed off the sensors, as well as excess enzyme conjugate. Within the wash fluid is a substrate for the alkaline phosphatase enzyme. The enzyme bound to the antibody/antigen/antibody sandwich cleaves the substrate releasing an electrochemically detectable product. The electrochemical (amperometric) sensor measures this enzyme product which is proportional to the concentration of CK-MB within the sample.

B-Type Natriuretic Peptide/BNP

is determined amperometrically using a two-site ELISA method. Antibodies specific for BNP are located on an electrochemical sensor fabricated on a silicon chip. Also deposited in another location on the sensor silicon chip is an antibody/alkaline phosphatase enzyme conjugate specific to a separate portion of the BNP molecule. The whole blood or plasma sample is brought into contact with the sensors allowing the enzyme conjugate to dissolve into the sample. The BNP within the sample becomes labeled with alkaline phosphatase and is captured onto the surface of the electrochemical sensor during an incubation period of approximately seven minutes. The sample is washed off the sensors, as well as excess enzyme conjugate. Within the wash fluid is a substrate for the alkaline phosphatase enzyme. The enzyme bound to the antibody/antigen/antibody sandwich cleaves the substrate releasing an electrochemically detectable product. The electrochemical (amperometric) sensor measures this enzyme product which is proportional to the concentration of BNP within the sample.

Total Beta-Human Chorionic Gonadotropin (β-hCG)

The i-STAT Total β-hCG test uses a two-site enzyme-linked immunosorbant assay (ELISA) method. Antibodies specific for β-hCG are located on an electrochemical sensor fabricated on a silicon chip. Also deposited in another location on the sensor silicon chip is an anti-β-hCG antibody/alkaline phosphatase enzyme conjugate specific to a separate portion of the β subunit of the hCG molecule. The system is capable of detecting whole molecule (intact) hcg as well as the free β subunit, but not the β core fragment (β subunit missing the carboxyl terminal end). The whole blood or plasma sample is brought into contact with the sensors allowing the enzyme conjugate to dissolve into the sample. The hCG within the sample becomes labeled with alkaline phosphatase and is captured onto the surface of the electrochemical sensor during an incubation period of approximately seven minutes. The sample, as well as excess enzyme conjugate, is washed off the sensors. Within the wash fluid is a substrate for the alkaline phosphatase enzyme. The enzyme bound to the antibody/antigen/antibody sandwich cleaves the substrate, releasing an electrochemically detectable product. The electrochemical (amperometric) sensor measures this enzyme product, which is proportional to the

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concentration of β-hCG within the sample. Also positioned on the silicon chip is a (conductivity) sensor to assess the hematocrit value of the sample. This value is required in the calculation of the β-hCG concentration in whole blood samples.

TCO$_2$

The measured TCO$_2$ test method is calibrated to the International Federation of Clinical Chemistry (IFCC) TCO$_2$ reference method with an algorithm based on the Henderson-Hasselbach equation, which uses pH, PCO$_2$, and ionic strength (Na) measurements.

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2. Tietz, N.W., Tietz Textbook of Clinical Chemistry, third edition, Ed. C.A. Burtis, E.R. Ashwood, W.B. Saunders Company, Philadelphia, 1999. Table 50-20, Appendix.

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Prepared By: Date:

Adopted: _____ Date: _____

Reviewed: _____ Date: _____

Reviewed: _____ Date: _____

Reviewed: _____ Date: _____

Revised:_____ Date: _____

i-STAT QC Log: Incoming QC

Cartridge Type:_____ **Lot No.:**_____ **Rec'd. Date:** _____ **Quant.:**_____ **Temp. Strip:**_____

Control Name: _____ **Lot No.:** _____ **Level:** _____ **Exp. Date:** _____ **CLEW:** _____

Test									
Range									
Results									
Results									

Control Name: _____ **Lot No.:** _____ **Level:** _____ **Exp. Date:** _____ **CLEW:** _____

Test									
Range									
Results									
Results									

Control Name: _____ **Lot No.:** _____ **Level:** _____ **Exp. Date:** _____ **CLEW:** _____

Test									
Range									
Results									
Results									

Lot/Shipment accepted by: _____ **Date:** _____

i-STAT QC Action Log

Date	Cartridge Type	Cartridge Lot No.	Date Rec'd.	Quantity	Test(s) Out of Range	Corrective Action	Operator

REV. DATE: 13-Feb-17   ART: 714446-00W

i-STAT QC Log: Expiration Date and Storage Conditions: Refrigerated

Date	Location	Cartridge Type	Lot #	Exp. Date	Quantity	Temp.	Action	Operator

i-STAT QC Log: Expiration Date and Storage Conditions: Room Temperature

Date	Location	Cartridge Type	Lot #	Exp. Date	Quantity	Temp.	Action	Operator

ART: 714446-00W

i-STAT Electronic Simulator Log for Analyzer, Serial Number:_____ **Year:**_____

Date	Time	Pass Fail	Simulator ID	Operator	Time	Pass Fail	Simulator ID	Operator	Time	Pass Fail	Simulator ID	Operator

ART: 714446-00W

i-STAT Electronic Simulator Action Log

Date	Time	Analyzer	Failure Code or Letter	Simulator ID	Action	Pass Fail	Operator

REV. DATE: 13-Feb-17   ART: 714446-00W